Health Care Financing

Special Report

Findings from the National Kidney Dialysis and Kidney Transplantation Study

Health Care Financing Administration

Health Care Financing

Special Report

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Findings from the National Kidney Dialysis and Kidney Transplantation Study is the first report designed to meet the critical need for information on the current status of chronic renal disease patients. This report highlights the results of the National Kidney Dialysis and Kidney Transplantation Study by focusing on five major areas: quality of life, rehabilitation, disability, quality of care, and cost of treatment. It is hoped that the results of this study will be used to formulate future health policies which adequately reflect the needs of the chronic renal disease patients, to insure the highest standards of practice within the medical community, and to promote the most efficient use of public resources.

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Health Care Financing Administration
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Lastly, a note is required on the principal project staff. I served as the Project Director although my co-investigators included Louis P. Garrison, Jr., L. Gary Hart, and Diane L. Manninen. Through our collective efforts this report was made possible. We collaborated throughout the entire research endeavor, even though two of the principal staff now have primary affiliations elsewhere. Dr. Garrison has joined the staff of Project HOPE in Millwood, Va., as a Senior Policy Analyst, and Dr. Hart is now a Research Associate in the Department of Family Medicine at the University of Washington. Both Dr. Manninen and I remain on the staff at Battelle, and we continue to pursue research on organ transplantation and medical technology.

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Findings from the National Kidney Dialysis and Kidney Transplantation Study

by Roger W. Evans, Ph.D., Diane L. Manninen, Ph.D., Louis P. Garrison, Jr., Ph.D., and L. Gary Hart, Ph.D.

Executive summary

In December 1980, Battelle was awarded a grant by the Health Care Financing Administration to conduct a study concerned with the quality of life, quality of care, rehabilitation, and health status of patients in the United States undergoing treatment for end stage renal disease (ESRD). In addition, insofar as possible, the study was to examine the costs associated with the treatment of chronic renal failure. Unlike many previous studies, this study was to consist of a comparative analysis of patients on four different treatment modalities—in-center hemodialysis, home hemodialysis, continuous peritoneal dialysis, and transplantation. The goal was to examine the dissimilarities among patients on the different treatment modalities, taking into consideration the fact that patients on each modality had a varying case mix. For example, it was recognized that patients on in-center hemodialysis were generally older and sicker than patients who had received kidney transplants. At the outset of the study, because of such case-mix complications, it was recognized as inappropriate to attribute dissimilarities in patient outcomes solely to the treatment modality patients were on. In short, the primary question was whether the dissimilarities among outcomes were due to case-mix factors or to treatment modality.

The ideal approach to answering this question would be a clinical trial wherein patients are randomly assigned to available treatment modalities. Unfortunately, such a clinical trial is fraught with several ethical dilemmas, the most significant of which is the element of randomization. A sufficient amount of information has now been accumulated on the indications for use of various treatment modalities, making it difficult to randomize patients. Some patients are clearly not good candidates for certain treatment modalities. For example, in-center hemodialysis is frequently a default modality for patients who cannot be transplanted or have complicating conditions that preclude home hemodialysis. Thus, it is both unrealistic and poor clinical practice to assign patients to treatment modalities for which they are considered unacceptable. A true randomized trial would essentially accomplish this and would therefore be considered ethically indefensible. Only if all patients were equally suitable for all treatment modalities would a randomized trial be considered acceptable.

In light of the foregoing, it was decided that an observational study was the only alternative to a randomized trial. An observational study differs from a randomized study in that there is no artificial manipulation of the study factor, which in this case was treatment modality. The major limitation of an observational study is that the investigators have only minimal control over the study situation and, as a result, the results of the study can be easily distorted by factors that have not been controlled. To deal with this situation, the investigators are forced to use more complicated multivariate data analysis techniques that afford some control over those factors that are felt to be important. For example, we were able to statistically control for selected patient case-mix factors. This does not mean, however, that all relevant case-mix factors were controlled.

There are two types of observational studies—descriptive and analytic. This study included elements of both types of observational studies. On the analytic side, we proposed and tested specific hypotheses about the relationships among patient case mix, treatment modality, and patient outcomes. On the descriptive side, we occasionally presented the results of the study without proposing explicit hypotheses. Such descriptive results are of interest, particularly in those areas where relatively little information has heretofore been available. The objective here was simply to extend our knowledge about particular topics in hopes that at a later date appropriate hypotheses could be formulated.

The National Kidney Dialysis and Kidney Transplantation Study underscored some of the more significant problems that are encountered with the widespread availability of complex life-saving technologies. These problems are not only clinical but are also social, economic, legal, and ethical. Various chapters within this report discuss these issues, some to a greater extent than others. Patient outcomes are clearly a major focus, as questions are increasingly raised about the benefits patients derive from both dialysis and transplantation. The concepts of cost-benefit and cost-effectiveness analysis are no longer obscure exercises contemplated by health economists and bold health care policymakers. Both cost-benefit analysis and cost-effectiveness analysis are viewed as imperfect tools that merely facilitate the making of decisions about the use of scarce health care resources. To this extent, the National Kidney Dialysis and Kidney Transplantation Study offered us a greater understanding of the benefits ESRD patients derived from the various treatment approaches available to them.

This report is organized according to several major subjects. In the first section, we begin by placing the problem of treating chronic renal failure into perspective. Both Chapters 1 and 2 of this section are intended to do this.

The second section is concerned with the study methodology. In particular, we describe the sample design and survey methodology. This is followed by a chapter which shows how our patient sample compares with the ESRD patient population as a whole. The last chapter in this section provides detailed descriptive data on the patient participants.

The third section of the report deals with the concept of quality of life. Here we present data on a vast array of quality of life indicators and then we present data on patient preferences for ESRD treatment modalities.

The fourth section of the report addresses quality of care. Here we have chosen to examine differences in hospital use by patients on each of the treatment modalities, and then we consider the drawbacks of renal transplantation, namely, extrarenal complications.

The fifth section of the report focuses on the functional impairments of ESRD patients and their health status as measured by the Sickness Impact Profile. These subjects are indeed extremely important and certainly provide some perspective on the rehabilitation potential of ESRD patients.

The sixth section of the report is entitled rehabilitation but its two chapters are concerned with the patients' labor force participation and with their socioeconomic status. These two chapters are particularly revealing. Because few ESRD patients are actually working, this is reflected in their overall economic status—many ESRD patients are poverty stricken.

The seventh section of the report is concerned with the costs of treating ESRD. It is in this section that secondary sources of data are linked with the primary patient data that we collected in order to evaluate the cost implications of patient case mix. Although there are many limitations associated with the secondary data, the results are rather interesting. In addition, we have chosen to examine the travel costs associated with the treatment of ESRD, a subject that has received very little attention in the literature.

Finally, the report concludes with some insights concerning the relationship of economic efficiency to treatment modality prescription. The inherent conflicts of providing the maximum quality of care at the least cost are shown to be problematic. If anything, this chapter shows that the future of the ESRD program is likely to be both clinically and socially complicated. To resolve the inherent dilemmas characteristic of the delivery of ESRD services, it is apparent that creative solutions must be sought. These solutions are clearly beyond the capabilities of casual observers, and they must reflect the joint efforts of clinicians, policymakers, and scientists.

Introduction

Chapter 1.
Background

Introduction

Over the past 2 decades, numerous approaches have evolved for the treatment of patients with chronic renal failure or end stage renal disease (ESRD). All forms of dialysis and hemofiltration represent kidney replacement systems. Not surprisingly, each of the available treatment modalities is viewed as being somewhat competitive with the others. It is also true, however, that each of the treatment modalities has evolved to meet the particular needs of various subsets of patients. For example, diabetics often have blood access problems that make peritoneal dialysis a viable and perhaps their only alternative. Similarly, home hemodialysis has evolved not only as a cost-saving approach to the treatment of renal failure but as a modality that is more compatible with the needs of patients who have extensive family support. Thus, the view now commonly espoused is that all forms of treatment for ESRD must be viewed as complementary rather than competitive. In this regard, the various modalities for treating ESRD are similar to prescription drugs, even though nephrologists and transplant surgeons may disagree.

It is evident that all forms of treatment for chronic renal failure are expensive, and that in most Western countries dialysis represents a considerable commitment of national health care expenditures. For example, in 1983 alone, the United States spent nearly $2.0 billion for the treatment of ESRD patients. The experience is similar to that of Western European countries. All of this has culminated in a nearly tireless search for a means by which to reduce overall government expenditures for treating renal disease. It is often assumed, although solid evidence is rather scarce, that kidney transplantation is the least costly approach to treating the patient with renal failure. Of the various dialysis modalities, home hemodialysis is often regarded as the least expensive, although proper accounting of numerous social costs associated with performing dialysis at home would add greatly to overall expenditures. For example, the time a person spends assisting the patient with home dialysis cannot be valued at zero, nor can the space occupied by dialysis equipment and supplies be considered as no cost. It is yet unclear as to what the precise costs of continuous peritoneal dialysis (CPD) are as these patients are frequently hospitalized and may spend upwards of 30 days per year in the hospital. At any rate, it is difficult to arrive at any firm conclusion as to which treatment modality is truly least expensive. Ultimately it depends on what are considered as legitimate elements of cost—both economic and social, direct and indirect.

From the patient's point of view, policymakers probably spend too much time discussing cost when the real issue is how to enhance the medical and social outcomes associated with the treatment of end stage renal disease. Many clinicians are also concerned about outcomes, and they agree that the emphasis on cost has become too great. Adapting to a life characterized by dependence on dialysis is difficult for most patients, and the ambivalence many patients express about dialysis is often translated into noncompliance and occasional disagreements with dialysis center staff. Even though transplantation frees most patients from the obvious constraints of dialysis, the transplant patient lives an uncertain life. Concerns about graft rejection and infection are inevitable. In fact, some dialysis patients find a life of dialysis preferable to the uncertainty associated with a transplant. In short, from the patient's perspective, transplantation is not always the treatment of choice.

Because dialysis and transplantation have gained acceptance as therapeutic modalities for the treatment of ESRD, there has been a general trend toward examining the outcomes of patients, other than survival. Frequently, discussion centers on patient quality of life or rehabilitation. In the United States, this has certainly been true, and the European Dialysis and Transplant Association (EDTA) in their annual report always includes an analysis of rehabilitation. The underlying question may very well be this: What are the benefits derived from the tremendous financial commitment made to the treatment of ESRD? As the concerns about costs have buoyed, not surprisingly, the question of benefit has also attracted attention. In a very real sense the issue at hand is one of cost benefit or cost effectiveness.

The National Kidney Dialysis and Kidney Transplantation Study was conceived of as an opportunity to bring together the data required to interrelate the cost of treatment, the outcomes of patients, and the association of each of these with the available modalities for treating ESRD. In order to accomplish this in a reasonable fashion, we felt that a national probability sample survey of dialysis and transplant patients in the United States was necessary. A research proposal was submitted to the Health Care Financing Administration (HCFA) to conduct such a study. Unfortunately, the research effort as proposed was expensive and clearly exceeded the limited resources available to HCFA for the conduct of research. HCFA, nonetheless, felt that a proposal to interrelate these factors—cost, outcomes, and treatment modality—was worthy of support and decided to fund a scaled-down multicenter study as proposed by our group. The plan was to involve 11 dialysis and transplant centers geographically dispersed across the United States. A sample of approximately 950 patients, stratified by treatment modality, was to be selected from these 11 centers.

To provide some perspective for this report, it is important to comment on the nature of the modalities available for the treatment of end stage renal disease, the historical significance of the issue of cost, and the recently emerged issue of patient outcomes. This is particularly important for those readers who are unfamiliar with either the medical treatment of end stage renal disease or its diverse economic and social implications.

Gradually, as with any health care technology, the complex medical and social issues associated with dialysis and transplantation have become both apparent and troublesome.

Treatment modalities

To the renal physician the methods of treating renal disease are all too familiar. It is recognized that most patients who are afflicted with ESRD have experienced reduced renal function over a period of time and, for many, the need for renal replacement therapy comes as an unpleasant necessity, but not a total surprise. In some patients it is possible to use dietary management to protract the period of time from the diagnosis of impending renal failure to the onset of dialysis. In fact, the preparation of the patient for dialysis usually begins long before they receive their first dialysis treatment. In particular, vascular access must be achieved for each patient prior to the onset of maintenance dialysis. Preferably, a few months before hemodialysis, an arteriovenous fistula (Cimino-fistula) is surgically constructed in the patient's forearm. If the patient's original veins are not suitable, a saphenous vein from the patient's leg may be transplanted. Other materials that can be used in performing a vascular access are bovine grafts, umbilical cord grafts, and the more preferred polytretrafluorethylene (PTFE) grafts. Bovine grafts tend to produce aneurysms, and the major problem with the PTFE graft is perivascular infection.

At precisely what point a patient should be placed on dialysis is by no means clear. The topic is rather controversial, but the general idea is to avoid uremic complications on the one hand but not expose the patient to unnecessary risks from the treatment on the other. Usually a remaining kidney function with a GFR (glomerular filtration rate) of 5 ml/min—in other words 5 percent of normal—is a useful starting limit except for diabetics who need dialysis earlier to avoid severe ocular complications (Colombi, 1983). The GFR can easily be derived from serum creatinine level by using a nomogram (age and sex of patient are taken into account). Clinical symptoms, however, such as increasing blood pressure, decreasing lean body mass, itching, epistaxis, nausea, and vomiting are important indicators of the necessity of renal replacement therapy.

Although hemodialysis is the mainstay therapy for patients with chronic renal failure, it is by no means the only treatment. Most patients, however, will have been on hemodialysis at some point during the course of their treatment. Other forms of dialysis include continuous ambulatory peritoneal dialysis, continuous cycling peritoneal dialysis, and intermittent peritoneal dialysis. As an alternative to dialysis, patients may also choose to receive a kidney transplant. Since the kidney is a paired organ, the donor may be a living person or, alternatively, a brain-dead cadaver. Patients who are likely to receive a kidney transplant within a very short time are now commonly placed on continuous ambulatory peritoneal dialysis until the operation can be arranged.

Patients who participated in the National Kidney Dialysis and Kidney Transplantation Study could be on one of several ESRD treatment modalities. These included home hemodialysis; in-center hemodialysis; continuous ambulatory peritoneal dialysis (CAPD) and continuous cycling peritoneal dialysis (CCPD), the two types of continuous peritoneal dialysis; or kidney transplantation. As alluded to above, there are substantial differences among these modalities. These differences are worthy of further comment.

Hemodialysis

Hemodialysis or blood dialysis can be performed at a dialysis center or the patient's home. The treatment itself does not differ, only the location where the hemodialysis is performed. A kidney machine is required for hemodialysis. Depending on the patient's renal function, dialysis is performed either two or three times each week for a period of approximately 5 hours per treatment.

Today proportioning systems are used almost exclusively in hemodialysis. These machines mix soft water with the dialysis solution to form the desired dialysis solution, which is warmed to body temperature (Colombi, 1983). A negative-pressure valve connected to a dialysate pressure monitor allows increased transmembranous pressure by adding negative dialysate pressure to positive pressure in the blood compartment. A blood leak is detected by a photoelectric-cell system on the dialysate back-flow site.

The blood side of the dialysis system includes bloodlines, blood pump, air detector, and above all the dialyzer itself, where the solute transport takes place across the semipermeable membrane. The efficiency of the filter is dependent on the quality and thickness of the membrane as well as the design of the dialyzer.

During hemodialysis, complications may originate from both the machine and the patient. The patient's most frequent problem is low–blood pressure (hypotension) arising from excessive or precipated volume withdrawal. Hypotension as a consequence of bleeding due to anticoagulants is an exception. Cardiac arrthymias and anaphylactic or septic shock are equally rare reasons for low–blood pressure during dialysis (Colombi, 1983).

Occasionally, patients experience increased blood pressure during dialysis that may be accompanied by headache, both of which are a sign of disequilibrium syndrome. The disequilibrium syndrome is also responsible for postdialysis syndrome—fatigue, inability to concentrate, muscular weakness, headache, and exhaustion. Because of these complications, patients may be unable to work after dialysis for several hours. To diminish the untoward side effects of dialysis, the treatment may be performed while the patient is sleeping.

Other complications associated with dialysis are due to the vascular access. Infections after cannulation may occur as well as thrombosis and bleeding. Aneurysmatic enlargement of the Cimino-fistula may give rise to cardiac failure, thromboembolism, or simply to local pain. Complications with the equipment may be due to insufficient water softening (hard-water syndrome), defective dialysate composition (hemodialysis), blood leak, air leak (air embolism), and coagulation with the extracoporeal circuit.

Clearly, although an effective means of treating ESRD, hemodialysis remains an imperfect form of treatment. The treatment is demanding, time consuming, and not without side effects, some of which are rather serious. Nonetheless, for the majority (88 percent) of patients in the United States, hemodialysis is the primary treatment modality.

In the United States, the selection of recipients for ESRD treatment is a rather simple matter. Unlike some European countries, the United States does not deny treatment to any patient on the basis of medical or social criteria. There is an effort made, however, to prescribe those treatment modalities from which patients are most likely to benefit. The matching of patients to treatment modalities is an important problem, one perhaps deserving more attention than it has received in the past.

Nearly all ESRD patients are considered as candidates for hemodialysis, although, as described below, there are certain patients for whom hemodialysis is an unrealistic alternative. Once hemodialysis has been agreed on as the best option for treating a given patient, it is reasonable to consider whether or not the patient could be dialyzed successfully at home (Baillod, 1983). The requirements for home hemodialysis are not unlike those of continuous peritoneal dialysis, another form of home dialysis.

In all cases, patients with secondary medical problems such as severe cardiovascular disease, which may be exacerbated by the actual hemodialysis procedure, are generally excluded as candidates for home dialysis. Baillod (1983) has shown, however, that young adults with severe physical handicaps such as blindness, deafness, and immobility can be accommodated on home dialysis.

Perhaps the greatest medical contraindication to home dialysis is any evidence of persistent lack of discipline and inability to comply. Unsupervised, inadequately motivated patients get into serious medical trouble.

In Baillod's (1983) estimation, three age groups need special attention when being considered for home dialysis—very small children, adolescents, and the elderly. Small children may be uncooperative and adolescents may have problems associated with the restriction of freedom. The elderly present the greatest problem when considering home dialysis. Chronological age is not an absolute contraindication. The older the patient, however, the more likely they are to have other medical problems that preclude home dialysis. Likewise, spouses may have problems that limit their ability to assist with dialysis. For patients who live alone, dialysis at home can be more problematic.

Marital status can be a consideration in home dialysis, particularly if the marital relationship is unstable. Home dialysis tends to intensify previous problems, stress the relationship, and even disrupt it.

Learning ability is important in home dialysis. Literacy is poorly correlated with adoption to new routines, however. While educational level can be a predictor of home dialysis success, the uneducated but motivated patient can be equally, if not more, successful in acquiring the routine procedures of home dialysis.

Household cleanliness or lack of it does not necessarily influence the quality of home hemodialysis or the health of the patient, but dirty, ill-kept equipment deteriorates very fast (Baillod, 1983). Home hemodialysis equipment also takes up considerable space, and special plumbing and fixtures are required for home dialysis.

As indicated here, not all ESRD patients are suitable for home dialysis. Patients must be carefully selected to assure the success of this modality. If patients' initial objections are strong, it is unlikely that they or their families will be able to accommodate home hemodialysis.

Continuous peritoneal dialysis

As noted above, there are two types of continuous peritoneal dialysis—continuous ambulatory peritoneal dialysis (CAPD) and continuous cycling peritoneal dialysis (CCPD). In terms of technique, these modalities differ to some extent. The distinguishing characteristics are important although both patient groups in the National Kidney Dialysis and Kidney Transplantation Study are combined and referred to as being on continuous peritoneal dialysis (CPD). Some analyses have been performed in which CAPD patients are compared with CCPD patients (Evans et al., unpublished manuscript).

Intermittent peritoneal dialysis (IPD) was the technological precursor to both CAPD and CCPD. Although it was recognized that certain patients did well on IPD, the modality was limited in application for logistical reasons (Mion, 1983). On IPD, treatment was considerably longer than a hemodialysis treatment. In 1978, a new era began when Popovich and coworkers (1978) published their clinical results on CAPD.

CAPD procedure consists of filling the peritoneal cavity three to five times a day with dialysate. The dialysate remains in the peritoneum for a period of 4 to 8 hours; during that time, the empty bag remains attached to the peritoneal catheter in order to avoid infection from disconnection. The 8-hour rhythm during the night allows the patient an ordinary sleep. Attaching the bag requires 5 to 10 minutes, and the solution, which contains dextrose, sodium, chlorine, calcium, magnesium, and other ingredients, takes 10 to 15 minutes to flow into the peritoneal cavity. The bag or bottle is held or attached to something higher than the indwelling catheter to permit gravity flow. The catheter then is clamped to prevent backflow (Johnson, 1981; Council on Scientific Affairs, 1982).

After 4 to 8 hours' (the latter during sleep) equilibration, the fluid—which now contains urea and other wastes—drains out by gravity into the plastic bag and its contents are disconnected, weighed, and discarded. A new bag is then attached with asceptic procedures, which are taught to patients during a training period of approximately 2 weeks.

A variety of complications are associated with CAPD, including hernias, hypervolemia and hypovolemia, hypokalemia, and obesity. The most serious side effect is an infection referred to as peritonitis. Peritoneal infection is defined as a cloudy dialysate outflow with 50 or more leucocytes per mm^3. As noted by Colombi (1983), abdominal symptoms such as pain, nausea, vomitus, diarrhea, and fever are frequent but not necessarily present. The treatment of peritonitis consists of short lavages, addition of antibiotics to the dialysate, and other measures.

It is now evident that potential CAPD candidates must be highly motivated and must have the intelligence to learn the techniques and apply them correctly. A patient must be healthy enough—that is, free of debilitating illnesses—to function physically and psychologically without assistance (Council on Scientific Affairs, 1982).

Continuous cycling peritoneal dialysis represents an interesting variation of CAPD. Two groups of investigators (Diaz-Buxo et al., 1981a; 1981b; Adams et al., 1981) have introduced this technique. One group refers to it as automated long cycle peritoneal dialysis (ALCPD).

Both of these methods are identical, and they reintroduce the use of a machine—namely a cycler that is programmed to deliver three or four exchanges of dialysis solution over a period of 9 to 10 hours at night. At disconnection in the morning, the dialysis solution remains in the peritoneal cavity for 12 to 14 hours (Drukker, 1983).

As noted by Drukker (1983), the results of this technique equal those of CAPD, and they are superior to that of IPD. Only one connection at night and one connection in the morning substantially reduces the risk of peritonitis. Drukker (1983) concludes that "...there has been too little time and experience to form an opinion on newer techniques like CCPD (or ALCPD)." However, Diaz-Buxo and colleagues (1981b) have concluded that CCPD:

- Provides excellent clearances.
- Can achieve a high rate of ultrafiltration.
- Provides a steady physiological state.
- Requires fewer connections than CAPD, under asceptic control.
- Allows better utilization of time, because there are no diurnal interruptions and it utilizes automated nocturnal cycles.
- Provides patients a high degree of freedom and mobility by utilizing portable equipment.

Based on the sparse data that are available, these conclusions appear to be warranted.

Transplantation

Many renal physicians consider kidney transplantation to be the "gold standard" for the treatment of renal failure. Unfortunately, many patients do not meet prevailing patient selection criteria. For example, over the past decade, the age distribution of the ESRD population has steadily increased. Also, the health status of persons coming to dialysis has declined remarkably. Both age and health status threaten the success of renal transplantation, even though there has also been a trend to transplant patients who are older and sicker. Cyclosporine, a new immunosuppressive agent, has clearly altered patient selection criteria and transplant protocols (White, 1982; Morris et al., 1983; Najarian et al., 1983; European Multicentre Trial, 1982; 1983; Canadian Multicentre Transplant Study Group, 1983; Macek, 1983; Beveridge, 1983). For example, it is now argued that tissue typing is no longer a serious consideration and that with improved cadaveric graft survival rates living-related donor transplantation should be discontinued.

Many standard texts are now available on kidney and organ transplantation, and it is difficult to do justice to this important ESRD treatment modality in this short space (Hamburger et al., 1981; Morris, 1979; Wood, 1983; Chatterjee, 1982; Novick, 1983). In the preface to his book on renal transplantation, Wood (1983) states the following:

> "Transplantation is the ideal treatment for chronic renal failure. The patient can be completely rehabilitated and freed from the practical and psychological problems of long-term dialysis. Although hemodialysis is a life-saving procedure, the dependence on the machine means a very restricted life-style. In addition, most patients on dialysis are infertile and anaemic—both problems that can be solved by a successful graft."

Novick (1983) arrives at a similar conclusion, but he also emphasizes the cost aspect of treatment. He states the following:

> "Although these two modalities (dialysis and transplantation) complement each other and must be tailored to the particular needs of individual patients, transplantation is the preferred form of treatment because of physical and psychosocial rehabilitation and a reduced cost."

While nephrologists undoubtedly agree to some extent with the foregoing statements they would also find them somewhat debatable. In light of donor organ constraints, however, it is unlikely that transplantation will ever replace hemodialysis as the most prevalent form of treatment for end stage renal disease.

As described above, kidney transplants are usually described according to the source of donor. For example, in living related donor (LRD) transplants, the graft is taken from a living person, usually a relative. Cadaveric donor transplants are transplants in which the source of the graft is a brain-dead cadaver. Generally, graft survival rates for LRD transplants are superior to those of cadaveric transplants.

The indications for kidney transplantation are the same, regardless of whether a LRD or cadaveric transplant is performed. The majority of transplant recipients have glomerulonephritis; many others have various metabolic diseases, collagen diseases, obstructive uropathy; and a much smaller percentage have tumors. Patients with tumors (e.g., Wilm's tumor) are not considered primary candidates, because of the likely recurrence of cancer.

Age can serve as a contraindication to kidney transplantation, particularly in patients over the age of 55 years. The emphasis here, however, is on physiological rather than chronological age.

The assessment of patients for renal transplantation is comprehensive. A careful history of every potential recipient is taken. Wood (1983) recommends that the following be considered:

Cardiovascular system

Check for features of cardiac failure and symptoms such as angina and intermittent claudication.

Urino-genital system

Establish whether the patient has had a history of urinary tract infection and detail any difficulties experienced with micturition.

Alimentary system

Inquire about symptoms of gastrointestional disorders that might be a problem after transplantation, in particular, features suggestive to peptic ulceration, hiatus hernia, gallbladder disease, or diverticular disease.

Previous infections

It is important to find out which infective problems the patient has experienced and, especially, whether a patient has had tuberculosis or has been in contact with close family members who have suffered from the disease. In patients who have been on peritoneal dialysis, the incidence of peritonitis should be recorded.

Previous surgery

Previous operations should be recorded from the patient's notes, with a detailed description of any urological procedures. It should also be established whether any anesthetic problems have been encountered at any time.

Family history

Relevant aspects of family history should be investigated, with the state of health of the siblings being of particular importance.

Current therapy

Details of current therapy should be listed, with an indication of how long the patient has been on treatment for conditions such as hypertension and whether the dosages of drugs have had to be increased to maintain a stable blood pressure.

Blood transfusion

A detailed transfusion history should be obtained, using case notes, any additional information from the blood bank, and careful questioning of the patient.

As the foregoing imply, not every patient with ESRD is a candidate for transplantation. Patients may be excluded from consideration for various reasons. Contraindications to kidney transplantation can be absolute but temporary, and others are considered relative.

Transplantation itself is not without risks. Transplant patients frequently experience complications during and following transplantation. The precise incidence of many of these complications is unknown. Both infection and rejection are the most immediate concerns of the transplant team, although a variety of technical complications after renal transplantation are also a concern. Belzer (1979) has classified these latter rather uncommon complications as follows: (1) vascular, (2) lymphatic, (3) urologic, and (4) general. A variety of other complications have been reviewed by Crosnier (1981), including bone disorders, vision disorders, hepatic complications, hypertension, gastrointestinal disorders, steroid diabetes, and psychiatric disorders. Many of these complications are discussed at greater length in Chapter 10.

Despite the complications associated with renal transplantation, it is apparent that many patients prefer transplantation to a life of dialysis. Occasionally, however, the extrarenal complications may become life threatening. Although many of these can be reversed or coped with, transplant recipients do return to dialysis and, in some instances, receive multiple transplants.

Patient outcomes

As of late, the outcomes of patients undergoing treatment for ESRD have come under increasing scrutiny. This was briefly noted above. The rationale is simple: What are the net benefits associated with dialysis and transplantation? Morris (1979) comments on this subject as follows:

> ''Dialysis and transplantation are costly treatments and in recent years every western country, faced with rapidly rising medical costs, has reflected about the cost-effectiveness of expensive therapies. Inevitably the spotlight has fallen on dialysis and transplantation. Is this justified?''

In the minds of many, this question is answered easily in the affirmative, but for others who are concerned about a reallocation of the health care dollar to preventive health activities, the answer is not so obvious.

The development of new health care technologies is interesting in that the primary outcome of interest, at least initially, is patient survival. If the technology is supposed to save lives, the question of foremost interest is ''does it?'' It took several years before this question could be answered affirmatively for both dialysis and transplantation. However, by the early 1970's both dialysis and transplantation were established as therapeutic modalities for the treatment of ESRD.

Having resolved the question of quantity of life, attention turned to the quality of patient lives. Early reports in the 1960's suggested that the future was somewhat dismal. From both a socioemotional and quality of life perspective, dialysis patients, in particular, were not doing well (Abram, 1968; 1969; Reichsman and Levy, 1972; Shambaugh et al., 1967; DeNour and Czaczkes, 1968; DeNour et al., 1968; Friedman et al., 1970; Goldberg et al., 1972). These findings were discomforting. The means to extend life were available, yet patient quality of life assessments were disconcerting. Occasionally, questions were asked as to whether ESRD treatment was really worth it.

Fortunately, many technological advances occurred in the 1970's, and as a result, the number of hours per week that a patient dialyzed went from 40 to about 15. The nature of the treatment changed to such an extent that dialysis became a much less unpleasant experience than it had been previously. Also, dialysis patients were no longer the medical anomalies that had attracted mass media attention. Dialysis units soon sprang up across the United States, particularly after the extension of Medicare benefits to patients with ESRD in 1972.

Because improvements occurred in dialytic therapy and because transplantation was rapidly emerging as the treatment of choice, by the late 1970's rehabilitation was emerging rapidly as the issue of the 1980's. In retrospect, it is now obvious that this should have come as no surprise. As early as 1964 Gombos and coworkers (1964) had used an objective measure of the performance status of ESRD patients. They found that the overall level of functioning of their patients improved, but dialysis had to be performed with increased frequency to maintain a high level of functioning (Ginn and Teschan, 1983; Freeman, 1983; Mathew et al., 1983). Others were to use similar techniques to measure functional ability (Siemson et al., 1972; Gutman et al., 1981).

Early studies of vocational rehabilitation also suggested that the future was not bright. The results of a number of these studies and separate analysis performed by the EDTA are summarized in Tables 1-1 and 1-2. Most surprising, perhaps, is the relative consistency in the findings of these studies whether conducted in the United States or abroad. For example, the European rehabilitation figures dating from 1978 showed that 37 percent of the male and 39 percent of the female hospital dialysis patients were employed full time, whereas 20 percent of the males and 31 percent of the females performed part-time work. Among the home dialysis patients, 64 percent of the males and 66 percent of the females worked full time and 12 percent of the males and 19 percent of the females worked part time (Ginn and Teschan, 1983; Brunner et al., 1979). Nonetheless, the results of studies in the United States were not quite as optimistic as those from Europe (Bryan et al., 1978; Burns and Johnson, 1976).

Brief consideration of recent events suggests that a renewed interest in the rehabilitation of the ESRD patient in the United States can be traced to the completion of a government report on the subject and the publication of what is now considered to be a key paper in the *New England Journal of Medicine* concerning the disability and employment status of ESRD patients.

In June 1980, the Office of the Inspector General (OIG) completed a report on the end stage renal disease program (Bean, Makowiecki, and Yessian; 1980). Based on that report, two categories of recommendations were made to the Office of the Secretary, U.S. Department of Health and Human Services, and the Health Care Financing Administration. Both categories of recommendations, equally noteworthy, indicated a concern about client rehabilitation. To provide some sense of

Table 1-1

Number of hemodialysis patients, place of dialysis, and employment status for selected data years, by source of data

				Employment status		
Study reference	Year	Number of patients	Place of dialysis	Full time	Part time	None
					Percent employed	
Baillod et al., 1969	1969	60	Mostly at home	92.0	—	—
Cameron et al., 1970	1970	24	Facility	77.0	—	—
		25	Home	92.0	—	—
Pendras and Pollard, 1970	1970	110	Home	73.0	24.0	3.0
Strauch et al., 1971	1971	178	Facility	28.9	—	71.1
Freyberger, 1973	1973	48	Facility	55.0	24.0	21.0
Reichsman and Levy, 1972	1972	25	Facility	56.0	—	44.0
Malmquist, 1973	1973	17	Facility	47.0	—	53.0
Foster et al., 1973	1973	21	Facility	47.0	—	53.0
Cadnapaphornchoi et al., 1974	1974	41	Home	36.5	31.6	34.7
DeNour and Czaczkes, 1976	1976	95	Facility	28.4	36.8	34.7
Disney and Row, 1974	1974	300	Facility	51.2	31.4	17.4
		123	Home	81.3	10.4	8.3
Brunner et al., 1976	1976	9,000	Facility	36.8	30.8	32.4
		2,500	Home	68.0	16.8	15.2
Bryan et al, 1978	1978	3,462	Facility	5.7	7.1	87.2
		1,198	Home	20.8	10.3	68.9
Tews et al., 1980	1980	227	In-center hospital	23.0	27.0	50.0
		65	In-center limited care	40.0	20.0	40.0
		190	Home	56.0	19.0	25.0

NOTE: Data are based on Czaczkes and DeNour (1978), with additions by the present authors.

Table 1-2

Percent of dialysis patients in each vocational rehabilitation category in 21 European countries, by country: 1979

Country	Able to work— Full time	Part time	But no work available	But pension is higher	Unable to work	Unable to care for self
	Percent of patients					
Total registry	36.6	22.8	11.9	12.9	13.9	1.9
Austria	37.9	11.0	13.8	14.8	18.6	3.8
Belgium	22.1	30.4	10.9	18.4	16.8	1.3
Bulgaria	13.0	17.0	19.0	36.0	15.0	0.0
Czechoslovakia	20.6	36.0	5.1	28.5	9.8	0.0
Denmark	34.9	18.1	7.2	7.2	28.9	3.6
Germany Federal Republic	27.7	18.7	15.7	13.6	20.7	3.6
Finland	10.2	37.3	1.7	15.3	30.5	5.1
France	38.6	22.4	12.4	14.1	10.7	1.8
German Democratic Republic	15.2	51.6	8.2	3.2	19.1	2.6
Greece	28.1	25.0	20.3	11.7	13.3	1.6
Hungary	17.8	26.0	15.1	30.1	11.0	0.0
Israel	44.6	24.3	12.6	9.9	8.1	0.5
Italy	62.9	17.5	7.1	6.7	5.1	0.6
Netherlands	18.2	28.3	17.0	9.1	25.9	1.4
Poland	19.3	35.1	7.9	24.6	12.3	0.9
Portugal	47.4	34.2	5.3	0.0	10.5	2.6
Spain	40.7	25.4	12.4	10.6	9.9	1.0
Sweden	12.1	27.1	7.1	16.4	30.0	7.1
Switzerland	19.9	47.4	8.7	7.7	14.8	1.5
United Kingdom	33.2	16.3	19.1	14.1	14.9	2.5
Yugoslavia	13.6	19.1	7.4	37.0	22.5	0.3

SOURCE: Colombi, 1983, p. 101.

historical perspective, the following are the specific recommendations contained in the report:

Category 1 (Procedural)

- Develop a policy statement that expresses the Departmental commitment to the rehabilitation of dialysis and transplant clients.
- Sponsor conferences that explore dependency-reducing strategies and approaches.
- Convene a top-level task force to identify programmatic initiatives that can be taken to further rehabilitation objectives.

Category 2 (Issues)

- Upgrade the practice of client education.
- Invigorate and broaden the assessment process.
- Enhance employment opportunities.
- Provide further support for home dialysis.
- Expand the opportunities for self-care in dialysis facilities.
- Minimize the role of hospitals in the treatment process.
- Provide social and recreational outlets for dialysis clients.
- Review the reuse issue.

Several months following the issuance of the OIG's report, a major publication appeared in the *New England Journal of Medicine* that describes work disability and functional impairment among patients with ESRD (Gutman, Stead, and Robinson; 1981). The major findings of that study reemphasized some of the points made in the OIG's report. It showed, for example, that of the approximately 2,500 patients in the study, only 60 percent of those without diabetes and 23 percent of those with diabetes were capable of a level of physical activity beyond caring for themselves. Moreover, only 25 percent of the patients worked outside their home.

The two preceding reports presented a rather dreary picture of the rehabilitation of ESRD patients, and they subsequently spurred enough interest in the topic that the Health Care Financing Administration (HCFA) established a special National ESRD Patient Rehabilitation Task Force. This, of course, was one of the recommendations contained in the OIG's report. According to Kelly (1981), the charge to the Task Force was to "...identify further programmatic initiatives which can be taken to further rehabilitation objectives." A more detailed "Statement of Purpose" of the Task Force is included in Appendix 1-A.

As the Task Force began its work, it became evident that there was no clearly agreed on definition of rehabilitation. In the literature, rehabilitation was often conceived of as the ability of a patient to return to work and, to a lesser extent, the patient's ability to function with minimal, if any, functional impairment (Chyatte, 1979). Although there were numerous reports in the literature concerning the employment status of ESRD patients, there were far fewer studies that focused on funcitonal impairment among ESRD patients. Surprisingly, there were no studies that had examined the availability and use of rehabilitation services by ESRD patients. This appeared to be a major deficiency because many patients require specialized services if they are to meet their full rehabilitation potential.

In many respects, HCFA's interest in the subject of patient rehabilitation was perhaps best exemplified by its decision to fund the National Kidney Dialysis and Kidney Transplantation Study in 1980. HCFA has often been viewed as a Government agency that is only concerned about the costs of the ESRD program. The NKDKTS indicates that this is not the case. The primary focus of the NKDKTS was to be on patient outcomes. Thus, although both the report of the Office of Service Delivery Assessment (Bean, Makowiecki, and Yessian; 1980) and that of Gutman and coworkers (1981) sparked national interest in the problem of ESRD patient rehabilitation, HCFA's research priorities at the time clearly revealed a timely interest in the subject as well.

Treatment modality costs

As the Federal agency responsible for administering the end stage renal disease program, HCFA remains concerned about how it can continue to provide ESRD services as cost efficiently as possible. As the total patient population continues to increase, from 58,924 patients in 1981 to 71,987 in 1983, program expenditures have increased concomitantly, from $1.5 million in 1981 to $1.7 million in 1983. Numerous attempts in the form of new regulations have been made to reduce or contain total expenditures, but these have been met with limited success (Eggers, 1984).

From the perspective of total program expenditures, it is reasonable for HCFA to introduce regulations that encourage the use of those treatment modalities that are least expensive. Unfortunately, this is not a simple matter. As alluded to previously, relatively little is known about modality-specific costs. Numerous analyses have been conducted, many of which are summarized in Table 1-3. Few of these analyses are as systematic and representative as one would like to see. As a result, the modality-specific costs of treating ESRD remain debatable. A recent report from the Council on Scientific Affairs (1982) offers the following comments on cost:

> "...the cost remains significant at approximately $30,000 per year for in-center dialysis, and $18,000 per year for home dialysis by 1980 estimates. Continuous ambulatory peritoneal dialysis could have a significant impact in view of a lower estimated cost of $15,000 per year."

As revealed in Table 1-3, however, a definitive conclusion as that stated above hardly seems warranted.

The studies reviewed in Table 1-3 underscore the need for detailed analyses of the modality-specific costs associated with the treatment of ESRD. Only recently has a report become available from HCFA that, to some extent, accomplishes this. Eggers (1984) does this through an analysis of data for 100,000 different people who were identified as Medicare beneficiaries with ESRD during the period 1974 through 1979. Eggers' analyses are based on the universe of ESRD patients covered by Medicare during those years.

Table 1-3

A summary of studies on the cost effectiveness of the treatment of end stage renal disease

Study	Objective	Cost data	Survival data	Results
1. Klarman et al. (1968)	To compare the relative cost effectiveness of center dialysis, home dialysis, and kidney transplantation.	Source: Gottschalk Committee, U.S. data Estimate: (1967 dollars) Center: $14,000 per year; Home: $5,000 per year; Transplant: $13,000 per procedure	Source: Gottschalk Committee, U.S. data Estimates: (by dialysis versus transplant) Dialysis—55.7 percent survival at 5 years Transplant—54.4 percent survival at 5 years	Cost per live year gained: Center: $11,600 per year Home: $4,200 per year Transplant: $2,600 per year $2,200 per year (quality-adjusted)
2. Comptroller General (1975)	To compare cost effectiveness of center versus home dialysis.	Not applicable	Source: European Dialysis and Transplant Association through 1972.	Source: Estimates: (1972 dollars) Center: $27,600 per year Home: first year $4,900 later years $7,000

Table 1-3 (Continued)

A summary of studies on the cost effectiveness of the treatment of end stage renal disease

Study	Objective	Cost data	Survival data	Results
3. Buxton and West (1975)	To compare cost effectiveness of hospital versus home dialysis.	Source: Two centers in Great Britain Estimates: (1972 prices) Hospital: $13,720 per year; Home: $6,615 per year	Source: European Dialysis and Transplant Association through 1972 Estimates: Hospital—53 percent at 5 years Home—67.1 percent at 5 years	Cost per life year saved: Hospital: $11,564 Home: $6,370 (discount rate: 10 percent)
4. Hoffstein et al. (1976)	To estimate and compare cost per dialysis for home, home training, limited care, satellite, and hospital.	Source: Five major dialysis centers in the United States. Estimates: (1973 prices) Gathered detailed expenditure data for several categories.	Not applicable	Annual cost: Self-care, home $6,729 Full care, center $16,520 Full care, hospital $24,738 Also estimates per session costs for self-care training
5. Warner and Kolff (1976)	To compare the costs of home versus center dialysis.	Source: Microcosting using input prices and Medicare charges Estimates: (1975 dollars)	Not applicable	Annual costs: Center dialysis: $23,400 Home dialysis: First year without technician: $12,898 First year with technician: $17,728 Succeeding year without technician: $10,044 Succeeding year with technician: $15,504
6. Stange and Sumner (1978)	To compare the cost effectiveness of facility dialysis, home dialysis, and cadaveric transplantation.	Source: Internal Management Reports of HCFA Estimates: (1976 dollars) Center Dialysis: First year: $17,000 Succeeding years: $15,400 Cadaveric Transplant: First year: $25,000 Succeeding years: $3,000, $2,000, $1,500, $1,500, etc. or $9,000 if unstable. Costs of rejecting: $10,000	Source: National Dialysis Registry Human Renal Transplant Registry (both U.S. data) Estimates: (as of 1976) Center: 61.6 percent at 5 years Home: 63.7 percent at 5 years Cadaveric Transplant: Patient: (51.0-60.0 percent) at 5 years Graft: (34.6-36.0 percent at 5 years	Cost per life year saved: Center: $26,550 Home: $16,987 Cadaveric: $15,007 $15,472 (Cost estimates were discounted at 5 percent of life years at 7 percent)
7. Plonski (1978)	To compare costs between home and facility dialysis.	Source: Estimates: Home: First year: $21,300 Succeeding years: $11,800 Center: $20,700	Not applicable	
8. Blagg (1978)	To discuss ESRD treatment in general and to provide figures on treatment at the Northwest Kidney Center.	Source: Northwest Kidney Center Estimates: (1977 dollars)	Source: Northwest Kidney Center All dialysis patients: 58 percent at 3 years Home patients: 74 percent at 3 years	Annual costs: Home dialysis: $11,566-$15,436 Center Medicare reimbursement: $23,400 (Does not include hospitalization costs)

Table 1-3 (Continued)

A summary of studies on the cost effectiveness of the treatment of end stage renal disease

Study	Objective	Cost data	Survival data	Results
9. Pearson et al. (1976)	To estimate and compare costs of home versus center dialysis prior to Federal funding.	Source: 12 facilities in Connecticut Estimates: Home: Gottschalk Committee	Not applicable	Center dialysis: $14,000-$15,000 Home: $5,610 per year (claimed 9 of 12 centers losing money)
10. Schippers and Kolff (1976)	To estimate and compare costs of center hemodialysis versus transplantation.	Source: Estimates: (1973 dollars) Center: Dutch health insurance companies Transplant: 2 Dutch hospitals	Not applicable	Center dialysis: $26,000 per year Renal transplant: First year: $18,000 Second year: $3,200 with functioning graft
11. Hampers and Hager (1977)	To compare home versus center dialysis, using examples of Northwest and Boston Kidney Centers.	Source: Boston Kidney Center Northwest Kidney Center as reported to Congress	Not applicable	Home dialysis: Boston: with partner: $18,635 per year without partner: $23,624 per year
12. Roberts et al. (1980)	To compare cost effectiveness of four ESRD treatment modalities.	Source: U.S. Federal Government Home dialysis: First year: $22,760 Succeeding years: $13,237 Center dialysis: $24,800 per year Living-related donor transplant: First year: $20,700 Second year: $1,500 Succeeding years: $500 Cadaveric transplant: First year: $23,400 Second year: $3,000 Third year: $1,500 Succeeding years: $750 Graft rejection Death: $9,000	Source: U.S. data from reports to National Dialysis Registry and Human Renal Transplant Registry Use age-specific rates (e.g., 3 years survival for those 31-45): Home dialysis: 64.4 percent Living-related donor transplant: 72.2 percent Cadaveric transplant: 49.2 percent	Cost per life year gained: Center dialysis: $24,800 Home dialysis: $13,274 Cadaveric transplant: $14,918 Living-related donor transplant: $7,709
13. Ludbrock (1981)	To compare cost effectiveness of hospital dialysis, home dialysis and transplantation.	Source: British Department of Health and Social Security Prices: (1976-77 British pounds) Exchange rate—$1.80.1 per pound Estimates available from author	Source: Graft and patient survival (by age groups) from European Dialysis and Transplant Association Dialysis-to-transplant transition from NE Thomas Regional Health Authority Probabilities available from author. Estimates: (by dialysis versus transplant)	Cost per life year gained: Hospital dialysis: $12,816-$10,216 Home dialysis: $9,296-$10,469 Transplantation: $5,866-$8,363 Ends of range based on high/low assumption of costs. Assume 7 percent discount rate

Table 1-3 (Continued)

A summary of studies on the cost effectiveness of the treatment of end stage renal disease

Study	Objective	Cost data	Survival data	Results
14. Kraukauer et al. (1983)	To project program cost effectiveness and total costs to HCFA under varying assumptions.	Source: HCFA reimbursement records Estimate: (1979 dollars) Dialysis: Maintenance $18,179 per year Entry: $1,025 per year Death: $5,432 per year Transplantation: Procedure: $16,273 per year Maintenance, functioning graft: $4,074 per year Return to Dialysis: $11,956 Death: $15,161	Source: Dialysis patients from HCFA; transplant survival from the Kidney Transplantation Histocompatibility Study Dialysis patient 5 years survival 33.4 percent Transplant patient survival: (not given explicity in article)	General finding: HCFA ESRD program total costs and enrollment over the next 8 years are insensitive to likely increased rates of transplantation due to cyclosporine, etc.
15. Eggers (1983)	To estimate program cost effectiveness of renal transplantation.	Source: HCFA reimbursement records Estimates: (1979 dollars)	Source: HCFA patient survival experience Estimates: (see Table II-12)	Finding: Renal transplantation is more cost effective from HCFA's point of view. Average cost per year over 5 years: Dialysis: $18,800 Transplant: $15,800
16. Belzer et al. (1982)	To report costs and survival for renal transplantation at one center by type of donor (cadaveric versus living-related) and by type of recipient (diabetic versus nondiabetic).	Source: University of Wisconsin Transplant Services, last 7 years Hospital costs: transplant (for rest of year): Cadaveric, diabetic: $15,317 ($7,561) Nondiabetic: $12,717 ($4,683) Living-related, diabetic: $12,633 ($4,104) Nondiabetic: $11,125 ($1,967)	Source: University of Wisconsin Transplant Data Patient survival at 5 years Cadaveric, diabetic: 70 percent Nondiabetic: 88 percent Living-related, diabetic: 82 percent Nondiabetic: 96 percent	Living related more cost-effective (over one year) than cadaveric Diabetic less cost-effective than nondiabetic.
17. Roberts et al. (1983)	To compare cost effectiveness of ESRD treatment modalities from HCFA's and society's point of view.	Source: HCFA reimbursement records for 1979 Center dialysis: $23,343 per year Home dialysis: Equipment: $15,400 Supplies: $17,399 Training: $3,034 Transplant surgery: $20,400 Cadaveric transplant followup: First year $6,000 Second year $4,800 Third year $2,900 Living-related donor transplant followup: First year $4,800 Second year $2,400 Third year $1,200 Graft rejection: $12,600 Transplant death: $9,000	Source: HCFA-ESRD-MIS records Rates are age specific; Example: 30-45 years of age, 5 year survival: Dialysis 50.3 percent Transplant: Living-related donor transplant: 91.8 percent Cadaveric transplant: 80.3 percent	Costs per life year: Center dialysis: HCFA: $23,300 Society: $29,200 Home dialysis: HCFA: $18,800 Society: $24,100 Cadaveric transplant: HCFA: $12,600 Society: $16,800 Living-related donor transplant: HCFA: $5,700 Society: $8,300

Table 1-3 (Continued)

A summary of studies on the cost effectiveness of the treatment of end stage renal disease

Study	Objective	Cost data	Survival data	Results
18. Salvateirra et al. (1979)	To analyze costs and outcomes for 466 patients at one center.	Source: Hospital costs for transplant patients at University of California-San Francisco for 1972-76	Source: University of California-San Francisco 466 patients from 1972-76.	Costs: First year Living-related donor transplants: $14,658 Cadaveric transplant: $16,574 Second year functioning graft Living-related donor transplant: $185 Cadaveric transplant: $1,120 Survival (1 year): Living-related donor transplant: 100 percent Cadaveric transplant: 90 percent

The total cost of care for a transplant patient in 1979 is outlined in Table 1-4. As Eggers (1984) notes, approximately 45 percent (or $15,629) was attributable to the hospital stay during which patients received their transplant. DRG's were not in use at the time these data were obtained, but the detailed breakdown of charges is instructive. Of the $21,951 in total charges, 19 percent was for accommodation (the average length of stay being nearly 30 days). Another 7 percent was for intensive care unit services (about 5 days per transplant stay were spent in ICU). The bulk of the charges (74 percent) was for various ancillary services. As described by Eggers (1984), laboratory services accounted for $3,910 (18 percent of the total) and other ancillary services that include kidney acquisition and dialysis treatments accounted for $7,662 (35 percent of total charges).

Table 1-4

Medicare covered charges, percent distribution of charges, reimbursement, and covered days for kidney transplant stays, by cost center: 1979

Cost center	Charges: Amount	Charges: Percent distribution	Reimbursement[1]	Covered days
Total	$21,951	100.0	$15,629	29.6
Accommodation	4,238	19.3	(3)	24.7
Intensive care or coronary care	1,445	6.6	(3)	4.9
Ancilliary	16,268	74.1	(3)	(3)
Operating room	1,422	6.5	(3)	(3)
Pharmacy	1,700	7.7	(3)	(3)
Laboratory	3,910	17.8	(3)	(3)
Radiology	809	3.7	(3)	(3)
Medical supplies	502	2.3	(3)	(3)
Anesthesia	263	1.2	(3)	(3)
Other[2]	7,662	34.9	(3)	(3)

[1] Reimbursements estimated by applying 1979 Medicare cost-to-charges ratio of .712.

[2] Includes kidney acquisition and backup dialysis.

[3] Not applicable.

SOURCE: Eggers, 1984, p. 35.

Table 1-5, also taken from Eggers (1984), shows Medicare reimbursements for home hemodialysis and for in-center hemodialysis patients. In 1979, home hemodialysis patient costs averaged $18,659 per person, or 21 percent lower than the average program costs of $23,591 for in-center dialysis patients. Eggers (1984) cautions that "...it is not possible to determine how much of this differential is a result of lower dialysis costs because much of the home dialysis costs are included with the physician/supplier costs." He does underscore the fact, however, that home patients use fewer hospital resources than in-center patients ($4,743 and $5,519, respectively), but he also acknowledges that home patients may be healthier than in-center patients. Despite this, it would appear that "...in 1979 the cost savings to Medicare of having patients dialyze at home was approximately $5,000 per person."

Eggers (1984) has also compared directly dialysis patient costs with transplant patient costs, as shown in Table 1-6. He notes that in 1979 transplant patient costs

Table 1-5

Per capita Medicare reimbursement amounts and percent distribution of amounts for end stage renal disease dialysis patients, by place of dialysis and type of service: 1979

Type of service	Place of dialysis: In-unit: Amount per enrollee	In-unit: Percent distribution	Home: Amount per enrollee	Home: Percent distribution
Total	$23,591	100.0	$18,659	100.0
Outpatient	14,506	61.5	6,427	34.4
Inpatient	5,519	23.4	4,743	25.4
Patient/supplier[1]	3,496	14.8	7,459	40.0
Other[2]	70	0.3	30	0.2

[1] Includes physicians' services and home dialysis treatments.

[2] Includes home health and skilled nursing facilities.

NOTE: Rates are based on person years of enrollment.

SOURCE: Eggers, 1984, p. 35.

Table 1-6

Per capita Medicare reimbursement amounts and percent distribution of amounts for end stage renal disease dialysis patients, by type of therapy and type of service: 1979

	Type of therapy			
	Dialysis		Transplant	
Type of service	Amount	Percent distribution	Amount	Percent distribution
All services	$21,325	100.0	$34,914	100.0
Outpatient	12,825	60.1	8,186	23.4
Inpatient	4,924	23.1	20,980	60.1
Physician/supplier[1]	3,521	16.5	5,722	16.4
Other[2]	55	0.3	26	0.1

[1] Includes physicians' services and home dialysis treatments.

[2] Includes home health and skilled nursing facilities.

NOTE: Rates are based on person years of enrollment.

SOURCE: Eggers, 1984, p. 36.

were 64 percent higher than dialysis patient costs. Eggers (1984) explains the results presented in Table 1-6 as follows:

> "...almost one-fourth of dialysis patient costs ($4,924) are for in-patient care episodes. Most transplant patient costs ($20,980) are generated through inpatient stay episodes. On average, transplant patients are hospitalized three times for a total of about 50 days during the year in which the transplant occurs (including the stay for the transplant). Transplant patients also have higher physician costs than do dialysis patients ($5,722 and $3,521, respectively primarily because of transplant surgeon's fees. According to the 1983 ESRD Annual Report to Congress, reimbursements for physicians' transplant services range between $1,387 and $2,300. Transplant patients also incur large outpatient (i.e., dialysis) costs as well."

Eggers (1984) provides an explanation as to why the latter is the case in his paper. He concludes his analysis, however, with some data on the cost effectiveness of kidney transplantation. As shown in Table 1-7, the results of this analysis show that the higher initial costs of transplantation are "paid back" in about 4 years in terms of person-life years and lower program costs when compared with the relatively constant costs of dialysis therapy. Eggers (1984) acknowledges that his analysis did not include consideration of variations in patient quality of life, but concludes that "If one assumes that a functioning transplant provides a patient with a higher quality of life, then the relative cost-effectiveness of transplantation is increased" (Table 1-7).

Although limited to a certain degree because it does not include all ESRD treatment modalities, such as CAPD which was relatively new at the time of his analysis, Eggers' analysis of modality-specific costs is the most extensive completed to date. It should well serve as the basis for future analyses of this type. Even this analysis, however, does not incorporate patient outcomes.

Table 1-7

Average per capita Medicare reimbursement amounts for end stage renal disease transplant patients, by patient outcome: 1979

Patient outcome	Reimbursement per person year
All transplants	$34,914
First year:	
Graft functioning	29,860
Graft failed	42,432
Death	60,679
2d year and over:	
Graft failed	30,189
2d and 3rd year:	
Graft functioning	4,074
All dialysis	21,325
Patient living	19,541
Patient died	28,253

NOTE: Rates are based on person years of enrollment.

SOURCE: Eggers, 1984, p. 37.

Conclusion

What should be apparent from the preceding discussion is the need for a large-scale multicenter study that relates to each other various patient outcome, cost, and treatment modality data. The NKDKTS represents an attempt to do this as comprehensively as possible. Yet, as with any study, obvious shortcomings have been identified, as the analyses have proceeded. Some of these shortcomings have been identified, as the analyses have proceeded. Some of these shortcomings are study design problems that were acknowledged at the outset of the study. In particular, it would have been desirable scientifically had it been possible to randomize patients to the available ESRD treatment modalities. Unfortunately, randomization presented unresolvable ethical dilemmas. Also, a longitudinal study would have been preferable to a cross-sectional study. Collection of data at one point in time offers only a snapshot of the complex social and medical milieu of the ESRD patient. Consequently, many scientifically intriguing questions go unanswered. For example, by the close of the study it was recognized that the importance of the treatment modality switching problem is undoubtedly underestimated by clinicians. Nonetheless, it was ultimately possible to use data on modality experience to examine modality preferences among ESRD patients.

Although a strong case has been made for interrelating outcomes, cost, and modality, inherent data problems have also limited certain aspects of the analysis process. Once again, adequate cost data have proven elusive. In its present form, existing cost data are inadequate to fully resolve the modality-specific cost issue. They are, however, adequate for estimating total program expenditures. There is absolutely no question that better data are required before modality-specific costs can be estimated. In addition, however, there are numerous problems in the conceptualization of costs that must be resolved. For example, is the time that the spouse of a home hemodialysis patient spends assisting in home dialysis a legitimate economic cost of providing dialysis, or is it a reasonable social cost that patients must be expected to bear? If the latter is true, should not in-center hemodialysis patients be expected to offset a portion of the labor costs associated with their care in a dialysis unit? Clearly, there are many difficult issues concerning cost that must be resolved, not all of which lend themselves to empirical analyses.

In the final analysis, the NKDKTS makes a strong case for further systematic studies that interrelate treatment, cost, and outcomes. Although no attempt has been made to explicitly ration the treatment of ESRD, occasions arise on which this matter is discussed. In general, there is little public sentiment for rationing, but the public is often posed with abstract issues to be decided individually. For example, people are rarely confronted with the more generic problems in medicine that raise the spector of rationing. Nonetheless, should the occasion arise when technological advancements in the treatment of ESRD become stagnated and the economic resources become increasingly scarce, then data must be available on which access-restrictive decisions can be based. Choosing from among candidates for ESRD treatment those patients that are most likely to benefit is neither an easy nor enviable task. With regard to such decisions, should they become necessary, a forum should be provided at which other resource allocation and rationing decisions can be debated. Of the considerably high technology in medicine that is now available, kidney dialysis and kidney transplantation remain among the most highly visible. To some extent, therefore, the treatment of ESRD has been unfairly criticized.

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Appendix 1-A. Task force statement of purpose

The task force is being formed to:

A. Act as a stimulus to galvanize health professional, public administrator, and private commitment to the rehabilitation of end stage renal disease (ESRD) patients.

B. Review the success of efforts currently underway by various groups and individuals to rehabilitate patients and examine the personal, professional, institutional, and system barriers and disincentives to greater patient rehabilitation.

C. Define the scope and terms of problems ESRD patients face which need to be addressed in order to enhance the level of rehabilitation of these individuals. Work toward a consensus regarding goals which ought to exist on national and local levels regarding rehabilitation.

D. Propose new or modifications to existing rehabilitation programs in order to better coordinate and integrate activities intended to enhance prospects of achieving the above goals. Recommend ways in which organizations or processes may be made to function more effectively.

E. Identify systematic data collection and analysis activities needed to improve HCFA's ability to monitor, evaluate, and enhance rehabilitation of ESRD patients nationally. Propose specific action steps HCFA may take to improve the likelihood and actual rehabilitation of ESRD patients.

F. Inform relevant parties of results of deliberations and act as a conduit for other information of interest and value in achieving the aim of increasing rehabilitation of patients.

Chapter 2.
Treating end stage renal disease

Introduction

The most comprehensive analysis of the end stage renal disease program of Medicare was completed by Rettig in 1980 (Rettig, 1980a; 1980b). Rettig's account is a detailed report of the first 6 years of the ESRD program in which he examines the implementation of the program and studies the mechanisms by which policy control is exercised within the Federal bureaucracy. The report illustrates very nicely the complex maneuvering that occurs when legislators, policymakers, physicians, and patient consumers attempt to avoid what Calabresi and Bobbitt (1978) have described as tragic choices. It is in this regard that Rettig (1980a) when answering the question "Why study the ESRD program?" notes that:

> "This program claims our attention because life-saving medical treatment is being provided to a very small number of beneficiaries at a very high cost to society, the result of public policy to affirm the value that life is beyond price even though such affirmation requires substantial public resources."

It is unnecessary to review in detail the legislative history of the ESRD program. Medicare benefits were extended to ESRD patients in 1972. As described by Rettig (1980a), the intent of Congress in passing the ESRD legislation was relatively clear—". . .the amendment was to provide access to life-saving therapy for all who needed it where the costs of treatment was beyond the means of practically all individuals." Rettig (1980a) further notes that: "In providing access, the underlying rationale was to resolve the 'tragic choice' between this allocation of scarce resources and the value of human life."

Growth and cost

In testimony before the Subcommittee on Health, Committee on Ways and Means of the United States House of Representatives, on February 9, 1984, Dr. Carolyne Davis, Administrator of the Health Care Financing Administration, observed that:

> "Medicare costs for ESRD patients were about $2.0 billion in 1982. This was about four percent of total program expenditures and represents about 13.0 percent of Part B expenditures. These expenditures were for 70,000 beneficiaries, or one-quarter of one percent of Medicare beneficiaries, and they have grown much faster than were originally projected when the law was passed."

Indeed, as Davis' testimony indicates, there has been a tremendous increase in total program (Medicare) expenditures as well as the total number of (Medicare) beneficiaries. For example, expenditures increased from $184 million in 1974 to $1.3 billion by 1980. Expenditures for 1984 are expected to be $2.1 billion.

Table 2-1 shows the concomitant increase in the number of dialysis and transplant patients by year. As shown, there were approximately 300 patients undergoing chronic hemodialysis in the United States in 1965. By January 1968, this number had increased to more than 800, and by early 1969 more than 1,000 patients were receiving treatment at approximately 250 dialysis centers. In January 1974, shortly after the Medicare ESRD program began, there were 11,000 dialysis patients; and by the end of 1974, this number had increased to 18,875. In June 1976, data reported by the U.S. Department of Health, Education, and Welfare indicated that there were approximately 24,500 dialysis patients (Evans, Blagg, and Bryan, 1981), and by the end of that year, 30,100 patients were on maintenance dialysis. Today, there are more than 70,000 patients on maintenance dialysis.

A similar increase occurred with respect to kidney transplantation (Table 2-1), and the largest increase in transplants immediately followed enactment of Section 2991. Since then, the number of kidney transplants has continued to increase; and during 1983, more than 6,000 kidney transplants were performed at 159 renal trans-

Table 2-1

Number of patients on dialysis or receiving kidney transplants, by year: 1951-83

Year	Total number of patients on kidney dialysis at year end	Total number of kidney transplants performed each year
1951-62	—	75
1963	—	163
1964	—	239
1965	300	305
1966	NK	338
1967	NK	448
1968	800	676
1969	1,000	838
1970	2,456	1,091 (1,460)
1971	3,482	1,616 (2,909)
1972	10,000	1,993 (2,852)
1973	11,000	3,017
1974	18,875	3,190
1975	22,000	3,730
1976	30,131	3,504
1977	32,435	3,973
1978	36,463	3,949
1979	45,565	4,271
1980	53,364	4,697
1981	58,770	4,883
1982	65,233	5,358
1983	71,987	6,112

NOTES: NK = not known. Numbers in parentheses reflect discrepancies in the literature.

SOURCES: Office of Technology Assessment, 1982; Health Care Financing Administration, 1980; 1981; 1984.

plant centers. The current distribution of ESRD patients according to treatment modality is shown in Table 2-2.

Although the actual cost per patient per year for treatment of end stage renal disease (when adjusted for the rate of inflation) has decreased, total program costs have increased tremendously (Lowrie and Hampers, 1981; 1982; Eggers, 1984). Over the years, the proportion of total Medicare funds allocated to the ESRD program has continued to increase, largely as a function of the growth in the ESRD patient population (Rettig, 1980a; 1980b). In 1978, ESRD benefit payments constituted 1.3 percent of the Hospital Insurance Trust Fund (Part A) and 8.9 percent of the Supplementary Medical Insurance Trust Fund (Part B). By 1982, 13.0 percent of the total Part B expenditures were allocated to ESRD patients, 4.0 percent higher than initially projected. In 1983, ESRD benefit payments accounted for an estimated 3.7 percent of the total Medicare expenditures (Parts A and B) and 8.5 percent of Part B expenditures (Eggers, 1984).

Because the ESRD patient population is not expected to stabilize in the near future (Eggers et al., 1984), it is expected that total payment costs will continue to increase. The estimated ESRD patient population and annual benefit payments, projected to 1991, are shown in Table 2-3.

In an attempt to better understand the continued actual and projected increases in the cost of the ESRD program, questions are being asked about the selection of patients for dialysis and transplantation. Over the past decade, the ESRD patient population as a whole, has become older and sicker, their rehabilitation potential is less, and the complexities associated with treating patients with multiple comorbidities may contribute to greater overall ESRD program expenditures.

Table 2-2

Number and percent distribution of end stage renal disease patients, by modality: 1983

Modality	Number	Percent distribution
Total	86,987	100.0
Dialysis		
Total	71,987	82.9
In-center hemodialysis	57,029	65.6
Home hemodialysis	4,323	5.0
Continuous ambulatory peritoneal dialysis	8,532	9.8
Intermittent peritoneal dialysis	745	0.9
Home peritoneal	790	0.9
Dialysis training	568	0.7
Transplantation		
All functioning grafts[1]	15,000	17.1

[1] These figures are estimates (Krakauer, 1983) derived from what is known about the survival of transplant patients and the number performed each year.

Table 2-3

Medicare end stage renal disease population, annual end stage renal disease payments, and income generated by second-payer regulations: Selected years 1974-91

Year ending September 30	Average annual enrollment in thousands	Total benefit payments in millions	Income generated by second payer regulations in millions
1974	16.6	$184	—
1975	25.3	327	—
1976	33.2	481	—
1977	40.3	654	—
1978	46.7	835	—
1979	53.9	1,037	—
1980	62.0	1,268	—
1981	68.2	1,532	—
1982	72.8	1,814	—
1983	76.8	2,056	—
1984	80.5	2,153	$10
1985	83.7	2,337	25
1986	86.7	2,561	35
1987	89.4	2,782	45
1988	91.2	3,004	55
1989	92.2	3,220	55
1990	93.0	3,437	60
1991	93.6	3,671	65

SOURCE: Health Care Financing Administration, Office of the Actuary: Data from the Supplementary Medical Insurance Branch.

Composition of patient population

In a paper published in 1981, Evans and coworkers (1981) examined the ESRD patient population at two points in time in order to speculate on the health policy implications of changes in composition of the patient population. Their analysis began with a brief discussion of how patient selection played a key role in passage of the ESRD legislation, an analysis that is particularly relevant today. They noted that:

> "Until 1973 there was substantial patient selection by physicians or committees, and although all ESRD patients had a terminal condition, some had better prospects for treatment than others. Patients, if not treated on a first-come, first-served basis, were selected for treatment based on a number of criteria. These included, for example, age, medical suitability, mental acuity, family environment, criminal record, economic status (income, net worth), employment record, availability of transportation, willingness to cooperate in the treatment regimen, likelihood of vocational rehabilitation, psychiatric evaluation, marital status, educational background, occupation, and future potential."

Clearly social class considerations and social worth often were more important in treatment decisions than other more equitable and less controversial criteria. In order to eliminate any access barrier, Medicare benefits were extended to all ESRD patients.

Comparing the ESRD patient population 4 years prior to passage of the ESRD legislation and 5 years after its enactment, Evans and coworkers (1981) found major changes in its composition. Table 2-4, reproduced from their report, shows that prior to Medicare, only 25 percent of dialysis patients were female, but by 1978 this figure increased to 51 percent. In 1967, 91 percent of dialysis patients were white, compared with 64 percent in 1978; the number of black patients increased from 7 percent of the population in 1967 to 35 percent in 1978. In 1967, dialysis patients on the whole were well-educated, and 25 percent had attained a college degree; in 1978, however, only 7.5 percent had done so. The average age of patients also changed dramatically before and after Medicare. In 1967, only 7 percent of dialysis patients were 55 years of age or over, but by 1978, this proportion had increased to 46 percent. In 1967, only 5.0 percent of dialysis patients were separated, divorced, or widowed, but by 1978, 25 percent were. Another very significant change was that in 1967, 42 percent of all dialysis patients were working, but by 1978, only 18 percent were.

Table 2-4

Percent distribution of the hemodialysis patient population, by social and demographic characteristics: 1967 and 1978

Characteristic	1967	1978	
	Percent distribution		
Sex			
Male	75.0	49.2	
Female	25.0	50.8	
Race			
White	91.0	63.7	
Black	7.0	34.9	
Other	2.0	1.4	
Education			
Junior high school or less	10.0	28.7	
Some high school	17.0	17.2	
High school graduate	27.0	28.4	
Some college	20.0	18.2	
College graduate	12.0	5.7	
Postgraduate school	13.0	1.8	
Unknown	1.0	0.0	
Age			
25 years	8.0	3.4	
25-34 years	24.0	10.0	
35-44 years	32.0	14.6	
45-54 years	27.0	25.8	
55 years	7.0	45.7	
Unknown	2.0	0.5	
Marital status			
Single	16.0	13.0	
Married	79.0	61.8	
Separated	—	6.3	25.2
Divorced	5.0	7.4	
Widowed	—	11.5	
Employment status			
Employed	41.7	18.4	
Unemployed	38.3	17.7	
Disabled	—	53.6	63.8
Student	13.2	Not coded	
Retired	—	10.2	
Other	0.0	0.1	
Unknown	6.8	0.0	

SOURCE: Evans et al., 1981.

These changes were consistent with the intent of the ESRD legislation—equal access was created for patients in need of treatment for chronic renal failure. The problem, however, has been that these changes have tended to limit the utilization of what are perceived of as the lower cost treatment modalities—home hemodialysis and kidney transplantation. Evans and coworkers (1981) made note of the following:

> "It is also evident, however, that the trend away from home dialysis as well as the higher cost of therapy are due in part to the changing composition of the hemodialysis patient population."

As shown by the following, they also suggested that medical considerations as well as sociodemographic factors were creating both cost and utilization problems:

> "There are also an increasing number of patients starting to receive dialysis who have diabetes mellitus or other serious medical problems. These factors along with age, combine not only to produce patients who are unsatisfactory candidates for home dialysis, but patients who are high users of other medical care services. Such patients are chronically ill, often requiring frequent hospitalization and a disproportionate share of other medical resources."

Such patients are among those most likely to receive disability benefits. The following was noted by Evans and coworkers (1981, p. 490-491):

> ". . .considering that these patients are among the least likely to be rehabilitated, the disability benefits they receive also add greatly to the total cost of their care. Thus, the cost of dialysis per se is but only one component of the total health care and social welfare dollar expended for patients in this category."

In 1980, Rettig (1980a) estimated that ". . .fully one-third of the ESRD beneficiaries are eligible for Social Security monthly disability (income support) benefits." Based on 1976 data, Evans and coworkers (1981) estimated that 36 percent of dialysis patients had total household incomes below the poverty level, and 46 percent of patients had household incomes lower than when they began dialysis. In a more recent analysis that was based on results from the National Kidney Dialysis and Kidney Transplantation Study, it has been determined that nearly two-thirds of the ESRD population is receiving Federal income support either through the Social Security Program or Supplemental Security Income. (Chapter 14.) The incomes of ESRD patients are substantially below those of the general U.S. population. Even with Federal income support, nearly one-third of ESRD patients are living in households with incomes below the poverty line.

In the absence of patient selection criteria, as described above, the overall status, both medical and social, of the ESRD patient population has declined. Nonetheless, it is inappropriate to rule the ESRD program as unsuccessful—success it seems is a relative notion. Rettig (1980) comments on this as follows:

> "In many ways the ESRD program is a success. Congress established it to pay for the treatment of individuals with kidney failure so that no one lacked access to life-saving treatment for financial reasons. Patients are receiving treatment, bills are being paid, and access to care is no longer an issue. Although program and individual treatment costs are high, the cost experience includes some encouraging aspects, and there is no reason to believe that quality of care has declined, even though more elderly and sicker patients are now being treated than before."

According to Inglehart (1982), Congress views the ESRD program similarly. In his words:

> "Politically, Congress views the ESRD program with some ambivalence. Generally speaking, the program is deemed a success because it pays for the treatment of patients with kidney failure who otherwise might have been denied such care."

Despite these indications of success, the future of the ESRD program may not necessarily be the same as its past, although the nature of any changes are by no means clear, nor are they being openly discussed at this time. As the future of the Medicare program has become increasingly uncertain, so have the prospects of the ESRD program.

Future program

It is difficult to speculate on the future of the ESRD program. Perhaps the best one can hope for is to identify the signposts for the future (Blagg and Scribner, 1980a; 1980b; Blagg, 1983; Relman and Rennie, 1979). Even though no overt attempt is being made at this time to invoke a structured set of patient selection criteria with uniform application, there are serious efforts being made to increase economic efficiency and, thus, to reduce the cost of the ESRD program. As alluded to above, twice in the 10-year history of the program Congress has enacted ESRD amendments to the Social Security Act (Inglehart, 1982).

The first set of ESRD amendments came in 1978. These were intended to accomplish the following five major objectives, according to a document published by the Senate Finance Committee (Committee on Finance, 1981, cited in Iglehart, 1982:493):

> "...to provide incentives for the use of lower cost, medically appropriate self-dialysis, particularly home dialysis, as an alternate to high-cost institutional dialysis; eliminate program disincentives to the use of transplantation; provide for the implementation of incentive reimbursement methods to assure more cost-effective delivery of services to patients dialyzing in institutions and at home; develop a long-range objective, on the basis of the continuing review and judgment of professional peer review organizations, with respect to the most effective use of resources for treating renal disease; and provide for studies of alternative ways to improve the program and for regular reporting to the Congress on the renal disease program."

As a result of the 1978 amendments, several optional incentives intended to increase the use of home dialysis and transplantation were introduced. These included early entitlement without the 2- to 3-month waiting period for patients entering self-care dialysis training, 100 percent of the cost of purchasing home dialysis equipment, and the establishment of target rate reimbursement for home dialysis. This latter provision provided for a home dialysis treatment to be reimbursed at 70 percent (later set at 75 percent) of the adjusted regional rate for outpatient dialysis. Despite these changes, outpatient dialysis remained relatively profitable and an easier form of care to deliver; and so, with the exception of the development of continuous ambulatory peritoneal dialysis, there was little increase in the use of home dialysis as a result of these amendments. Even worse, from the cost-containment viewpoint, the number of outpatient dialysis facilities, chiefly hospital facilities, with exceptions to charge more than the standard rate continued to increase; and by 1982 about one-half of all hospital dialysis units had such exceptions.

The second set of ESRD amendments were approved by Congress as part of the Omnibus Budget Reconciliation Act of 1981 (Blagg et al., 1982a; 1982b). These amendments were intended to establish a dual-rate reimbursement system that differentiates between hospital-based and freestanding dialysis facilities, to promote home dialysis and transplantation, and to strive for other improvements in efficiency in the program. The new regulations were published in the *Federal Register* on February 12, 1982, as a Notice of Proposed Rulemaking. This resulted in a storm of responses from organizations, professionals, and patients, that were related especially to the question of whether there should be a dual rate or a single rate for both hospital and freestanding units, and also the level of reimbursement set, as this was based on outdated audit data from 3 to 5 years before.

While the new regulations would continue to provide for exceptions, control of the process for granting exceptions would be much tighter. Also included in the package was a significant change in the method of physician reimbursement for care of ESRD patients. The overall goal remained the same—to reduce Federal costs through the promotion of home dialysis. In a memorandum to then Secretary of the U.S. Department of Health and Human Services Richard Schweiker, Dr. Carolyne K. Davis, Administrator of HCFA, noted the intent of modifying the current method of paying physicians:

> "In consideration of our goal to stimulate home dialysis, we do not believe it is sufficient to place our emphasis solely on facilities to generate the desirable shift to more home dialysis; it is likely that equal or greater incentive belongs with the physicians."

Despite the barrage of comments, the proposed regulations were published in final form on May 11, 1983. As a result, the National Association of Patients on Hemodialysis and Transplantation (NAPHT), the Renal Physicians Association (RPA), and a freestanding dialysis facility joined forces to sue the Government in an attempt to block the implementation of the new regulations. As of June 1984, the judge ruled that HCFA had set the rates at a reasonable level, and the judge believed that HCFA would monitor quality of care and safety carefully. However, certain other changes related to physician reimbursement and coverage were decided in favor of NAPHT and the other organizations. Currently, the U.S. Department of Justice is considering an appeal based on the question of whether the courts have jurisdiction over procedural issues related to Part B of the Medicare program—a precedent of great significance to health care generally.

Meanwhile, the intent of the Government remains clear—to contain costs through creating greater efficiency in the ESRD program. However, there is a limit to the degree to which increased efficiency can be fostered, and more drastic solutions may be in the offing. Dr. Constantine Hampers (cited in Iglehart, 1982), commenting on the 1981 amendments, speculated that:

> "...the implications of the proposal will be devastating to beneficiaries. Even now, people are speculating that this is an attempt by HHS to emulate the English health care system, under which few patients over the age of 55 are accepted for treatment (dialysis)."

The suggestion that some version of the British system may be adopted in the United States for the treatment of patients with ESRD, as well as other types of patients, is not completely unrealistic. Although such a suggestion is not being entertained either in Congress or by officials of the Health Care Financing Administration at this time, there is growing concern that such a major overhaul of the health care system may be inevitable (Iglehart, 1983; 1984).

It is noteworthy that over the past 2 years the British system of delivering ESRD services has come under fierce attack, primarily by the British patient's association but also by nephrologists responsible for patient care (Anonymous, 1984; Wing, 1983; Iglehart, 1984). There have been several recent papers in the *British Medical Journal* that reflect this trend, including a report on the successful treatment of kidney patients over 65 years of age, and a paper arguing why blind diabetics should be offered dialysis. Iglehart (1984) notes that even popular television has been attracted to the issue, but then concludes:

> "Thus far, though, there is no general evidence of change in the restricted availability of dialysis treatment in Britain. The officials at the Department of Health and Social Security with whom I discussed this issue said that any appreciable increase for renal dialysis simply is not a priority at this time."

In the end, the winds of change may prevail, however. Diana Brahams, a British barrister, has examined the "doctor's duty and the patient's right" in the treatment of end stage renal failure. The British Kidney Patient Association (BKPA) estimates that between 2,000 and 3,000 deaths occur each year in Britain from renal failure, many of which are unnecessary. The BKPA has decided to escalate their efforts to attain more dialysis services for those in need and has recently announced that the next patient refused treatment by the National Health Service (NHS) and who is brought to their attention will be treated privately at the Association's expense. Bills for the patient's treatment subsequently will be presented to the NHS; and if they are not paid, in Brahams (1984, p. 3856) words, the BKPA "...is prepared, apparently, to take the Secretary of State to court—presumably for failing to provide necessary treatment as required under the National Health Service Act, the private hospital bills amounting in effect to damages."

In her analysis Brahams notes that refusal to treat a patient can occur because the patient is too old and sick to be treated, or there is a lack of facilities at which patients can be treated. To argue that a patient is untreatable because of a lack of facilities is clearly questionable:

> "It seems to me that a doctor who tells a patient that he is untreatable because of the lack of facilities, is failing in his duty of care. Surely he should tell the patient that there would be a chance for him if he could receive the correct treatment and that he should seek it in a different health area which may have greater facilities."

She then goes on to concede that:

> "After all, dialysis is nothing experimental and new; it is not an extraordinary way of keeping people alive only in one or two centres of the world; it is a treatment offered all over the UK and the industrialized world. On the other hand, the doctor may argue that if the patient is unlikely to find alternative treatment in a different region, then what is the point of upsetting both him and his family? Might it not be kinder and simpler to tell them that the condition is incurable and must be accepted? Yet, in so doing, the doctor is misinforming the patient and depriving him of the chance at least of receiving alternative care and any other legal options as yet untried that may be open."

Brahams (1984) makes it clear that in the future it may become increasingly difficult to deny ESRD patients dialysis or transplantation, regardless of their social and medical characteristics. Perhaps the decision will ultimately rest with the courts. Her concluding remark is as follows: "As pleas for change by press and doctors and patients fail to elicit any positive response, the only alternative route seems to lie through either the criminal or the civil arm of the law—though such a course is dogged by expensive uncertainty."

Those close to the ESRD program in the United States have become fearful that a variation of the British system of rationing by simple exclusion ultimately may be adopted, perhaps on the basis of age and comorbidity. Thus, even though there has been support for initiatives to reduce total program expenditures, there is also an implicit fear that there is a limit to which such reductions can be made without affecting quality of care and/or access to treatment. Also, it is recognized that although technological developments may effectively reduce future program expenditures, no promising developments appear on the horizon at this time.

Conclusion

If anything, the controversy surrounding the selection of patients for dialysis and transplantation has served to focus attention on patient outcomes. As noted in Chapter 1, survival is a valuable indicator of patient outcomes, but there are certainly other issues involved. Satisfactory patient benefits must be judged on more than survival alone. Though survival may be the most immediate concern of patients undergoing dialysis and transplantation, their long-term concern is the qualitative aspect of their existence. The argument commonly offered for restricting access to dialysis is that certain groups do not benefit qualitatively from treatment, even though their lives have been extended years beyond what would have been expected if the disease had not been treated.

The remainder of this report will primarily address the qualitative aspects of the end stage renal disease patient experience. The goal is to divert attention away from the issue of cost, at least initially, and then to close by introducing the cost issue, but making certain that patient outcomes are placed in proper perspective. Unfortunately, our health care system can no longer be considered apart from the tremendous costs that are incurred in delivering health care. For many years health care providers have ignored cost as a primary issue. This has all changed now and from the perspective of many physicians, cost is the primary issue. Perhaps this report will strike a reasonable balance between health care costs and patient benefits.

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Methodology

Chapter 3.
Sample design and survey methodology

Sample design

A two-stage sample design was followed in the National Kidney Dialysis and Kidney Transplantation Study. The first stage in the sampling process was to enlist the participation of 11 dialysis and transplant centers across the country. The selection of these centers was purposive, random. The 11 participating centers represent a mix of characteristics such as region, profit status, university affiliation. Unlike a national probability sample of centers that would have produced a sample representative of the population of dialysis and transplant centers, however, a purposive sample is designed to include sufficient numbers of observations from certain subgroups (dialysis and transplant centers) in the population to allow comparisons to be made with statistical reliability (Kish, 1965; Warwick and Lininger, 1975; Selltiz et al., 1976).

Once the number of patients at each center was ascertained they were stratified by treatment modality and a target sample size was established, taking into consideration the overall objectives of the study. The goal was to be certain to include an adequate number of patients on each modality to allow for statistical analysis. A potential "center effect" was minimized by disproportionately selecting patients from the centers. Unfortunately, but not surprisingly, a large number of patients came from a few centers.

The reason for selecting a purposive sample of dialysis and transplant centers was largely one of cost. Conducting personal interviews with a probability sample of kidney dialysis and transplant patients selected from a probability sample of dialysis and transplant centers would have been very expensive. Because of limited resources, a purposive sample of centers was viewed as the best strategy, reflecting the various tradeoffs among the costs of data collection, the representativeness of the sample, and the multiple objectives of the study. The major advantage of the purposive sample of centers, of course, is that it is possible to obtain sufficient numbers of patients from various treatment modalities by interviewing a smaller number of patients at a limited number of dialysis and transplant centers. However, a purposive sample is a nonprobability sample, and as such, inferences from this sample of centers to the entire population of dialysis and transplant centers in the United States must be considered tenuous. This matter will be discussed further in Chapter 4.

Sample size

Estimates of the required sample size were based on the characteristics of the dialysis and transplant patient population, the incidence of patients who work, and the desirability of estimating models concerning the quality of care and quality of life of dialysis patients. Based on the available information on the characteristics of dialysis patients (Bryan et al., 1978; Evans, 1979; Bryan and Evans, 1980a; 1980b; Evans et al., 1981), a sample of 950 patients was deemed sufficient for purposes of the study. This sample would provide at least 100 patients for the smallest subsample to be analyzed in the study. This was considered sufficient for the study's objectives, given the increases in cost associated with expanding the sample.

The target sample size of 950 patients was divided among the four modalities as follows:

- 325 incenter hemodialysis patients.
- 325 home hemodialysis patients.
- 150 continuous peritoneal dialysis (CPD) patients.
- 150 transplant patients.

The former two groups were given larger target sample sizes for several reasons. First, differences in return to work between these two groups was a major focus of the study, and these sample sizes were determined to be necessary for that analysis.

Second, a target sample size of 150 CPD patients was sufficient for the analysis of quality of life, disability, rehabilitation, and quality of care. In addition, this sample size subsumed the available CPD population at the 11 centers so that a greater size would call for more centers and greater costs. (It was learned later that there were only 140 CPD patients available at the beginning of the survey.) Third, the target size for transplants was chosen to be sufficient for the major analyses, but was not set as high as those for home or incenter in part because of the greater cost and difficulty of obtaining these interviews. The ties of transplant patients to the centers are obviously not as strong as those of dialysis patients.

Selection of centers

The 11 dialysis and transplant centers agreed to participate in the study included Downstate Medical Center (Brooklyn, N.Y.), Northwest Kidney Center (Seattle, Wash.), Dallas Kidney Disease Center (Dallas, Tex.), Nalle Clinic (Charlotte, N.C.), Eastern Maine Hospital (Bangor, Maine), The Kidney Center (Boston, Mass.), Presbyterian Medical Center (Denver, Colo.), West Contra Costa Dialysis Clinic, Inc. (San Pablo, Calif.), Bishop-Clarkson Memorial Hospital (Omaha, Neb.), Indiana University (Indianapolis, Ind.), and Dialysis Clinics, Inc. (Nashville, Tenn.). These 11 sites were selected to maximize variation among them across the following criteria:

- Geography (State and region).
- Type (limited care, full-care, or both).
- Ownership (for-profit, nonprofit, or State government).

- Size (number of dialysis stations).
- Academic affiliation (university based or nonuniversity based).
- Availability of a home training program.
- Number of patients by modality (home, in-center, CPD, transplant).
- Service area (urban or rural).

Besides reflecting the diversity of major institutional features of the end stage renal disease (ESRD) delivery system, these characteristics were seen as possibly having direct and indirect impacts on the quality of life and quality of care of patients. Of course, this sample design, with only 11 centers, dictates that the patient rather than the center be the unit of analysis. Eleven observations (centers) are simply too few for meaningful analysis.

The distribution of the selected facilities across these characteristics are shown in Table 3-1, and it shows that the sample possesses characteristics that are important for the analysis. Facilities of various types and sizes have been included. Previous attempts to enlist the support of large for-profit facilities for research studies have been difficult. However, this sample includes the Dallas Kidney Disease Center of Dallas, Tex., and The Kidney Center of Boston, Mass., both large, for-profit facilities owned and operated by National Medical Care, Inc. This enhances the usefulness of the information obtained. Another source of concern is the number of patients who dialyze at home. Only about 6.0 percent of all dialysis patients in the United States are currently on home hemodialysis (HCFA, 1984). At the time of the study, 16.1 percent of all dialysis patients were on home hemodialysis (HCFA, 1982). To insure that adequate numbers of these patients were included in the subject pool, facilities were selected within States that have a large proportion of their patients dialyzing at home (e.g., Indiana, North Carolina, and Washington). A sufficient number of CPD and transplant patients were also available for analysis. Patients undergoing CPD training or home hemodialysis training, a small portion of the population, were omitted from the study.

Stratification

Prior to data collection, patient rosters were obtained to determine the population by modality at each center. The current treatment modality of each patient was noted on the list. The total number of patients by modality at each center based on these lists are shown in the first four columns of Table 3-2. There were a total of 3,739 patients on the four modalities at the 11 centers, of whom 2,419 (65 percent) were dialysis patients. Of the 11 participating centers, the three largest (Northwest Kidney Center, Dallas Kidney Disease Center, and The Kidney Center) accounted for 65 percent of all the patients.

Given the initial target sample sizes described above (i.e., 325 incenter hemodialysis, 325 home hemodialysis,

Table 3-1

Characteristics of the 11 sample dialysis and transplant centers

	Services provided			Type of ownership			Size	University affiliation		Type of treatment				Training	Service area			Type of center		
Center	Limited care	Full care	Both	For profit	Not for profit	State government	Number of dialysis stations	University-based	Nonuniversity-based	Home hemodialysis	Incenter hemodialysis	CPD	Transplant	Home training program	Urban	Rural	Combination	Hospital	Hospital with satellite	Freestanding
										Number of patients										
Northwest Kidney Center			X		X		38		X	221	271	28	228	X			X			X
Dallas Kidney Disease Center			X	X			40		X	45	611	24	232	X	X					X
Nalle Clinic		X		X			50		X	44	205	30	92	X		X				X
Eastern Maine Hospital		X			X		16		X	0	38	0	0			X		X		
Presbyterian Medical Center			X		X		28		X	33	72	7	0	X	X				X	
West Contra Costa Dialysis Clinics, Inc.		X			X		42		X	0	29	0	0		X				X	
Downstate Medical Center			X			X	45	X		68	16	0	257	X	X			X		
The Kidney Center			X	X			65		X	90	269	3	0	X			X			X
Bishop-Clarkson Memorial Hospital		X			X		22		X	2	45	4	174	X			X	X		
Indiana University		X				X	15	X		86	21	41	98	X			X	X		
Dialysis Clinics, Inc.			X		X		30		X	22	87	8	239	X						X

NOTES: Based on data provided at the outset of the study. CPD is continuous peritoneal dialysis.

Table 3-2

Number of persons in patient population, target sample, and actual sample, by treatment modality and participating center

	Population				Target sample					Actual sample				
Center	Home hemodialysis	In-center hemodialysis	CPD	Transplant	Home hemodialysis	In-center hemodialysis	CPD	Transplant	Target total	Home hemodialysis	In-center hemodialysis	CPD	Transplant	Actual total
Total	611	1,664	144	1,320	951	325	325	140	151	859	287	347	81	144
Northwest Kidney Center	221	271	27	228	236	104	80	27	25	221	104	80	11	26
Dallas Kidney Disease Center	45	611	24	232	179	45	85	24	25	179	31	103	20	25
Nalle Clinic	44	205	30	92	118	35	35	30	18	77	19	31	18	9
Eastern Maine Hospital	0	38	0	0	10	0	10	0	0	9	0	9	0	0
Presbyterian Medical Center	33	72	7	0	38	17	14	7	0	34	14	14	6	8
West Contra Costa Dialysis Clinics, Inc.	0	29	0	0	10	0	10	0	0	10	0	10	0	0
Downstate Medical Center	68	16	0	257	64	25	16	0	23	64	24	17	0	23
The Kidney Center	90	269	3	0	102	46	53	3	0	105	51	52	2	0
Bishop-Clarkson Memorial Hospital	2	45	4	174	35	2	9	4	20	32	1	9	2	20
Indiana University	86	21	41	98	98	35	6	37	20	77	34	5	18	20
Dialysis Clinics, Inc.	22	87	8	239	61	16	17	8	20	51	9	17	4	21

NOTE: CPD is continuous peritoneal dialysis.

150 continuous peritoneal dialysis (CPD), and 150 transplant), the desired sample size for each modality and at each center was determined as follows. First, because only 140 CPD patients were available, all were to be contacted. Second, at each site three primary sampling units (PSU's) were designated: one for patients who dialyze at home, one for patients who dialyze at the facility, and one for transplant patients. Third, the sampling fraction (target size or population) was calculated for each of these three modalities was multiplied by the modality population to determine the size that would be needed for a self-weighted sample using a uniform sampling fraction (Kish, 1965).

It later became clear, however, that this weighting might produce some undesirable effects because of the predominance of one treatment modality at some centers. Target sample sizes were then adjusted to reduce this effect, taking into account the costs of data collection and the new burden this might place on interviewer assignments at the participating centers. Thus, the second stage is best regarded as a stratified sample (treatment modality by center), with unequal sampling probabilities in each cell. In other words, all patients associated with the participating centers were randomly selected, and each patient in a particular modality and center (i.e., cell) had an equal probability of being included in the study. The exception were those patients not included in the initial sample frame because they were too sick to participate in a lengthy interview. The final target sample sizes shown in Table 3-2 reflect these minor adjustments.

Final sample selection

Given the target sample sizes and the list of patients at the centers, a random sample was drawn (using a random number table) for each cell in the strata and an initial target sample list was prepared. Only those patients 18 years of age or over were included for selection. Potential exclusion or nonresponse was handled by oversampling at a 20-percent rate for each cell, and preparing a potential replacement list of these patients. Thus, if a particular patient was unable (exclusion) or unwilling (nonresponse) to be interviewed, another patient on the same treatment modality was substituted from the replacement list in the sample. The individuals on this replacement list were contacted only if necessary. Although there were many exclusions, mostly because of therapy changes, in general, nonresponse (i.e., unwillingness to participate) was not a problem.

The surveying of patients began in November 1981 and extended through April 1982. To assure that the patients in the group had been stabilized on their current modality, patients who had changed treatment modality just prior to the data collection period were not included in the sample. As shown in Table 3-2, the final actual sample sizes achieved were 287 home hemodialysis patients, 347 in-center hemodialysis patients, 81 CPD patients, and 144 transplant patients. These sizes were certainly sufficient for purposes of the study, although the dropout rate for CPD patients was particularly troublesome. Slightly fewer home and slightly more in-center patients, relative to the target size, were surveyed. As indicated, the number of willing and available CPD patients was 81, far below the number the centers had initially indicated were on CPD. Of these 81 patients, 20 were on continuous cycling peritoneal dialysis and 61 were on continuous ambulatory peritoneal dialysis. The actual number of transplants surveyed fell only slightly short of the target size and was evenly divided between those with grafts from living-related donors (N=74) and those from cadaveric donors (N=70).

The ad hoc adjustments described above were only partly successful. Thirty-six percent of the final home hemodialysis sample was from the Northwest Kidney Center (as compared with 33 percent of the home population), and 29 percent of the final in-center hemodialysis sample was from the Dallas Kidney Disease Center (as compared with 40 percent of the population). Furthermore, 59 percent of the 859 sample patients on all modalities came from three centers, the preceding two plus The Kidney Center in Boston.

Data collection instruments

Several data collection instruments were developed specifically for the study. These instruments included the following:

- Chronic Renal Disease Patient Interview Schedule.
- Chronic Renal Disease Patient Health, Medical Care, and Treatment Expenses Diary.
- Chronic Renal Disease Patient Medical Records Data Abstraction Form.
- Dialysis and Transplant Center Survey.

Each of these instruments is briefly described below.

The Chronic Renal Disease Patient Interview Schedule was the primary data collection instrument. Questions in this survey instrument focused on the following areas:

- Current regimen of treatment and satisfaction with that mode of therapy.
- The patient's feeling of well-being and satisfaction with life in general.
- Limitations on daily living—both current and prior to the onset of kidney disease.
- Social and family relations.
- The impact of the patient's condition on family relations.
- The impact of the patient's condition on marital relations.
- Employment status—both current and prior to the onset of kidney disease.
- Health status—summary of recent illnesses and hospitalizations, frequency of symptoms.
- Experience with various Government programs.
- Rehabilitation services.
- Sources of payment for medical expenses.
- Current financial situation.
- Sickness Impact Profile—a standard instrument to measure current health status.

At the end of the interview, patients were given the Patient Health, Medical Care and Treatment Expenses Diary and were asked to maintain it for the next 30 days. In addition to a daily record of how closely they followed their diets, how much they exercised, and how well they felt, patients were asked to keep a record of illness behavior, utilization of health services, and medical expenditures. Information from the diary was to be used to assess the medical needs of people with chronic renal disease. The diary was also intended to be of help in identifying out-of-pocket expenses associated with the treatment of end stage renal disease that were not included in standard cost estimates, such as amounts spent for telephone, housekeeping, babysitter, or travel services.

The Patient Medical Records Data Abstraction Form was used to abstract pertinent data from the patient's medical chart (with the patient's written consent). Interviewers recorded such basic information as the date kidney treatment was initiated, primary diagnosis, whether or not the patient had ever received a transplant or was currently awaiting one, and the patient's regimen of routine care. In addition, data were recorded on comorbid conditions a patient had and to what extent these resulted in physical impairment. Finally, an assessment was made of the patient's ability to work.

Although the above three instruments focus on patients and their experience with end stage renal disease and its treatment, the fourth survey instrument provided essential descriptive data on the participating dialysis and transplant centers where the respondents received treatment. The Dialysis and Transplant Center Survey was mailed to each of the 11 centers participating in the study. Questions in the survey focused on various characteristics of the participating centers, including treatment schedules, patient and treatment loads, staff qualifications, rehabilitation services, and finances.

In addition to the data collected using the four survey instruments, data was obtained on Medicare-billed charges for each Medicare-eligible patient included in the study. These data are maintained through the Health Care Financing Administration's End Stage Renal Disease Medical Information System.

Taken together, these data sources provided the information necessary for a comprehensive analysis of the current status of chronic renal disease patients in this country.

Data sources

Although the patient was the primary source for most of the data, additional data were provided by the patient's nephrologist, transplant surgeon, renal nurse, renal social worker, and in some instances the administrator of the dialysis or transplant center. Table 3-3 provides a complete breakdown of each survey instrument, showing all possible sources of data. It should be noted that the data sources varied across centers. For example, at some centers the patient's nephrologist may have provided the basic medical data; and at other centers, a renal nurse was fully capable of providing the necessary data. Despite variation according to data source, each on-site data collector was responsible for coordinating the data collection effort. The principal investigator and his staff, was responsible for determining which source was most appropriate for providing which

Table 3-3

Data collection instrument, by data source

Collection instrument	Patient	Nephrologist	Surgeon	Nurse	Social worker	Administrator
Chronic Renal Disease Patient Interview Schedule	X					
Chronic Renal Disease Patient Health, Medical Care, and Treatment Expenses Diary	X					
Chronic Renal Disease Patient Medical Records Data Abstraction Form		X	X	X	X	
Dialysis and Transplant Center Survey		X	X	X	X	X

data. For example, if the renal nurse could provide the required data, it was unnecessary to contact the patient's nephrologist.

Data collection

Collection agreements

Prior to the collection of any data, each participating dialysis and transplant center entered into a formal or informal data collection agreement with Battelle Human Affairs Research Centers, Seattle, Wash. The nature of the data collection agreements varied from one center to another. Several centers entered into a subcontract with Battelle, and these centers hired their own data collectors. At two centers Battelle entered into a personal services agreement with existing dialysis and transplant center staff. At these centers, existing staff were paid by Battelle, on a part-time basis, to conduct data collection activities during their time off. At several centers Battelle either located a person to do the data collection or was assisted by center staff in locating a person who was then hired by Battelle on a part-time basis to undertake the data collection activities. Finally, at one center, Battelle staff were used to conduct the interviews and abstract the medical records data. This approach was adopted when it became apparent that the person originally identified as the data collector at the center would be unable to complete the data collection activities prior to the deadline.

A total of 16 people were hired as data collectors. Of these 16 people, 6 were independently experienced interviewers and 10 were dialysis and transplant center staff members. The 10 included 3 social workers, 4 nurses, 1 dialysis technician, 1 psychologist, and 1 transplant coordinator.

Collector training

To assure the quality of the data collection effort, all data collectors came to Seattle for an intensive 2½ day training session. The major objective of the training session was to review the purpose of the study, introduce the data collectors to principal project staff, review the data collection procedures, enable the interviewers to become familiar with the survey instruments, and to practice administering the patient survey. In addition, senior project staff provided an introduction to and a review of basic social research interviewing techniques. Data collectors were also given special training in administering the Sickness Impact Profile.

An extensive procedures manual (Evans et al., 1982) was developed by principal project staff to serve as a field guide for the data collectors. In addition, the procedures manual served as a guide during the training session; and it was frequently referred to both during and after data collector training. The manual was divided into several major sections, each of which was periodically updated during the course of the study as the need arose. The major sections of the manual were as follows:

- Organization.
- Protocol.
- Criteria.
- Data Collection at Each Site.
- Sampling Procedures and Target Rates for Each Site.
- Travel Recordkeeping.
- Excerpts From the Institute for Social Research Interviewer's Manual (University of Michigan).
- Question-by-Question Specifications—Chronic Renal Disease Patient Interview Schedule.
- Question-by-Question Specifications—Chronic Renal Disease Patient Medical Records Data Abstraction Form.
- Question-by-Question Specifications—Chronic Renal Disease Patient Health, Medical Care, and Treatment Expenses Diary.
- Dialysis and Transplant Center Survey.
- Patient Consent Forms.
- Data Collection Instruments (Sample Copies).

The manual was thorough in terms of its coverage of all aspects of the study.

Following training, the coordinating center staff at Battelle maintained regular telephone contact with the data collectors. All data collectors were strongly encouraged to call principal project staff at Battelle at any time with questions about procedures, any difficulties they had in conducting interviews or abstracting medical records, or, if needed, for general moral support.

Contacting patients

At a majority of the participating centers, the prospective respondents were notified by a letter from the medical director that the National Kidney Dialysis and Kidney Transplantation Study was being undertaken with the center's support and that they might be contacted by a data collector to be interviewed for the study. These notices were typically ''blanket'' notices, because dialysis and transplant center staff were not always aware of which patients were selected for the study. Participation was also encouraged via articles printed in the renal patient's newsletters which are published by some centers (e.g., Northwest Kidney Center).

Each data collector was provided with a target sample list and a replacement list of names specific to each treatment modality at the close of the training session. If a person in the target sample was unable or unwilling to participate in the study, the interviewers contacted, in the order given, patients from the alternate list until they located a patient who was willing to take part in the study. When both lists of names were exhausted, the data collectors were instructed to call the principal project staff at Battelle who would provide them with additional names randomly drawn from the patient rosters. This procedure assured that a random sample of patients was obtained.

During the interviewer training session, each data collector was encouraged to begin interviewing assignments on returning home by contacting those patients who only infrequently visit the dialysis or transplant center (e.g., home hemodialysis and transplant patients). The goal was to make certain that an acceptable time for an interview could be agreed upon before the conclusion of the data collection period.

During the initial contact with a prospective respondent, the data collector briefly described the study objectives and what participation in the study involved. If a patient was willing to take part, an appointment was scheduled to conduct the interview at the dialysis or transplant center, the patient's residence, or some other mutually convenient location. If a patient was unable or unwilling to participate or did not meet the selection criteria, the data collector recorded the reason on an exit form and contacted an alternate respondent from the replacement list.

Interviewing and abstracting procedures

During the initial contact, each respondent was provided with two consent forms. The General Patient Consent Form outlined the study objectives, the potential risks and benefits of participating, and the guarantees of anonymity and confidentiality. A signed General Patient Consent Form was a prerequisite for conducting the interview. In addition, the patient was given a medical records consent form entitled ''Authorization for Review of Medical Records.'' Although all patients were asked to consent to a review of their medical records, agreement was strictly optional.

All interviews were conducted in a manner consistent with the guidelines set forth in the procedures manual described above (Evans et al., 1982). Patient interviews averaged approximately 90 minutes in length, with some taking as long as 120 minutes. Generally, the patients found the interviews interesting and, overall, a stimulating experience.

After the interview, the data collector explained the purpose of, and instructions for, filling out the Health, Medical Care, and Expenses Diary during the next month. Respondents were encouraged to call the on-site interviewer or one of the Battelle staff members about any questions they might have; and they were asked to return the diaries in a self-addressed, postage-paid envelope that was provided.

Information about the respondent's medical history, current treatment, and hospitalization history was gathered by the data collector from the dialysis or transplant center's medical records, hospital admission records, and personal physician when necessary. A member of the medical staff who was familiar with the respondent's condition was asked to evaluate the respondent's degree of disability resulting from comorbid conditions and to rate the patient's general functional status on the Karnofsky Index (Karnofsky and Burchenal, 1949; Gutman et al., 1981). An assessment of the respondent's ability to work or undergo job training was completed by the staff social worker.

Data processing

Data collectors returned groups of completed interviews, medical record abstraction forms, and exit forms to Battelle by mail or United Parcel Service. To maintain anonymity, signed consent forms were returned separately from the completed data collection instruments. Respondents mailed their Medical Care and Expenses Diaries directly to Battelle in postage-paid envelopes.

Converting field work into a final data tape for analysis involved several important steps, all of which were completed under the supervision of a senior research scientist assigned to this specific task. First, a data control system was established to ensure accurate handling and preparation of data without delay. Under this system, logs for each center and patient were maintained based on weekly reports from interviewers and receipt of completed work, thus providing weekly status reports. Following log-in, completed instruments were coded and manually edited, then batched for keypunching and data entry. Because the patient questionnaire primarily consisted of closed-ended items that could be precoded, coding efforts and potential transcription errors were minimized. Quality control was exercised on an ongoing basis through amendments to the coding key and verifications of the coder or editor's work.

All data were keypunched directly from the data collection forms that were formated to facilitate this. After keypunching, the data were read into the computer and stored on disk with several back-up tapes. Finally, computer programs were initiated to perform item-by-item data cleaning operations, including logic and range checks. Errors were manually reviewed, corrected, and resubmitted for a machine edit. This cycle of edit, correct, and re-edit was repeated until each batch of instruments was reported to be error-free and a clean data tape was produced for analysis.

Nonresponse and patient exclusion

Exits by reason for exclusion

Patients were excluded from the study for several reasons, including the following:

- Death.
- Withdrawal by patient preference.
- Relocation.
- Social or emotional problems.
- Medical problems.
- Age (patient under 18 years of age).
- Recent change in treatment modality.
- Patient in home hemodialysis or CPD training program.
- Not needed.

The number of exits by reason for exclusion for each of the 11 participating centers is shown in Table 3-4. As can be seen from the table, of the returned exit forms, 53 patients (11.4 percent) died between the time the patient list was prepared and the time that the interview was to be scheduled. Participation in the study was strictly voluntary, and 101 patients (21.7 percent) withdrew by their own preference (resulting in a nonresponse rate of approximately 10 percent).

Relocation was the reason for the exclusion of 113 patients (24.3 percent). This group consisted of patients who moved from the study area (and hence changed dialysis centers) or lived too far away, making a personal interview infeasible. This situation occurred most often at those centers with large home hemodialysis or transplant programs, because these patients do not need to make frequent visits to the dialysis or transplant center. Attempts were made to schedule an interview with such patients if they visited the center during the data collection period. However, in light of the expense associated with traveling to the homes of patients to conduct interviews, patients were excluded from the study if they lived more than 1-hour's driving time from the center. In some cases, interviews were conducted with patients who lived at greater distances if several interviews could be scheduled on one trip.

A decision was also made to exclude patients with specific social, emotional, or medical problems. Such decisions were generally made by a physician or other staff member at the dialysis center. Social and emotional problems included language problems, mental retardation, severe behavioral disorders, or other conditions that would lead one to question the ability of the patient to understand and provide meaningful responses to the interview. Medical problems include any serious conditions that would make it impossible for the patient to

Table 3-4

Number of returned exits, by treatment modality, reason for exclusion, and participating center

		Treatment modality				Reason for exclusion								
Facility	Total	Home hemodialysis	In-center hemodialysis	CPD	Transplant	Death	Patient preference	Relocation	Social or emotional	Medical	Age	Change in modality	Training	Not needed
						Number of exits								
Total	465	171	174	49	71	53	101	113	35	37	17	81	1	27
Northwest Kidney Center	185	93	54	16	22	17	24	62	10	10	8	36	0	18
Dallas Kidney Disease Center	83	18	45	5	15	15	16	14	8	4	2	18	0	6
Nalle Clinic	27	2	10	13	2	3	7	1	1	2	3	10	0	0
Eastern Maine Hospital	2	0	2	0	0	0	1	0	1	0	0	0	0	0
Presbyterian Medical Center	25	13	10	2	0	5	7	5	3	3	0	2	0	0
West Contra Costa Dialysis Clinics, Inc.	2	0	2	0	0	1	1	0	0	0	0	0	0	0
Downstate Medical Center	3	1	2	0	0	1	1	0	0	0	0	0	1	0
The Kidney Center	55	20	34	1	0	4	24	14	3	9	0	1	0	0
Bishop-Clarkson Memorial Hospital	13	0	4	0	9	0	6	5	0	0	2	0	0	0
Indiana University	34	11	1	9	13	5	4	1	8	7	0	6	0	3
Dialysis Clinics, Inc.	36	13	10	3	10	2	10	11	1	2	2	8	0	0

NOTE: CPD is continuous peritoneal dialysis.

complete a rather lengthy personal interview. If a person was reported to be ill at the time of initial contact, repeated attempts were made to schedule an interview at a later date. Thus, this category was used only as a last resort for making every attempt to conduct an interview. Of those patients who were excluded from the study, only 35 (7.5 percent) were excluded for social or emotional reasons, and 37 (8.0 percent) were excluded for medical reasons.

Patients were also excluded because they failed to meet certain patient selection criteria. The study focused on patients with end stage renal disease who were 18 years of age or over. According to the returned exit forms, 17 patients (3.7 percent) were excluded from the study because they were under 18 years of age. Also, as was discussed earlier, to assure that the patients in each group had been stabilized on their current treatment modality, patients who had changed modality just prior to the data collection period were excluded from the study. According to the exit forms, 81 patients (17.4 percent) had changed modality after the initial patient list was prepared, and 1 (.2 percent) was in a home or continuous peritoneal dialysis training program during the data collection period.

Finally, a small number of patients whose names were drawn (27 patients or 5.8 percent) were not included in the study because the desired number of interviews in that cell had already been completed (i.e., interviewers had met their quota of interviews for that modality).

Exits by treatment modality

In addition to presenting the number of exits by reason for exclusion, the number of exits by treatment modality for each of the 11 participating centers are also shown in Table 3-4. As can be seen in the table, the number of exits were distributed across the four different modality groups, with the numbers of exits from the home hemodialysis group being approximately equal to the number of exits from the in-center hemodialysis group.

The most important of these numbers, however, is the number of exits for continuous peritoneal dialysis (CPD). Because the sample design did not include a sample from the CPD population, but was to be a census of CPD patients, no replacements were available for the patients from this group who were excluded from the study. In several instances, similar problems occurred in attempting to obtain the desired number of home dialysis patients at centers with very small home hemodialysis programs. Indeed, this is the primary reason that the actual number of completed interviews fell short of the target number of interviews for the CPD and home hemodialysis patient groups.

Response rates

The overall response rate for the two major patient-related data collection instruments was excellent. Completed Chronic Renal Disease Patient Interview Schedules and Chronic Renal Disease Patient Medical Records Data Abstraction Forms were obtained for 90 percent of the patients who were ultimately considered eligible for the study. Unfortunately, the response rate for the Chronic Renal Disease Patient Health, Medical Care, and Treatment Expenses Diary was low, despite the fact that the diary was closely patterned after a general health diary previously designed and pretested extensively by the Survey Research Laboratory at the University of Illinois (Sudman and Lannom, 1980). Only 337 diaries were completed and returned, resulting in a response rate of 40 percent. At the outset, it was acknowledged that response to a diary was likely to be lower than desired, primarily because of two factors—the data the patients were asked to record were fairly complex, and the length of time (1 month) that the patients were asked to keep the diary was probably excessive.

All of the participating dialysis and transplant centers completed and returned the Dialysis and Transplant Center Survey. Some centers chose not to provide certain data that they felt were confidential, and other centers failed to provide data because the responses to the questions were unknown. For example, some centers were unable to provide current survival rates for transplant recipients.

Study design limitations

Several limitations of this study design deserve mention. First, as noted earlier and elaborated on in Chapter 4, there is the problem of potential nonrepresentativeness since the 11 participating centers were not selected randomly. Instead, they were chosen purposively to reflect various institutional characteristics as well as to ensure each center's full cooperation in the complex data collection activities. It is therefore inappropriate to assume that the estimates based on this sample can be directly generalized to the entire population with end stage renal disease (ESRD). This caveat is given even greater strength by noting that 3 of the 11 centers provided 59 percent of the patients in the final sample. On the other hand, the 3 centers have very different characteristics, and thus provide substantial variability in areas important to the study. Ultimately our major objective was not to make very detailed comparisons across dialysis and transplant centers to assess unique ''center'' effects, but rather to estimate quantities for the entire sampling frame. More detailed comparisons across individual centers or centers grouped on some common variable (e.g., for-profit versus nonprofit centers) would only be realistic if the centers and patients both had been selected on the basis of probability sampling procedures (and with a much larger number of centers). In this case, it would have been possible to infer the sample results to the entire ESRD patient population.

Briefly, the major implications of this sample design for the analyses are as follows: For descriptive population statistics, weighting on a post-stratified basis is required for generalization to either the entire ESRD population or to the population of patients associated with the 11 centers. Generalization to the entire ESRD population is, of course, a risky endeavor because the 11 centers, even after post-stratification, may not fairly represent the population of all centers. For the behavioral analyses, weighting is not required. The correlations between treatment modality and quality of life, for example, should be a good estimate of that relation for the 11 centers. Again, the validity of such parameter estimates for the entire Nation is open to question.

A second major limitation arises in the attempt to make cross modality comparisons. Because individuals are not randomly assigned to treatment modalities, there is a selection bias. Individuals with the advice of their physician choose the treatment modality on which they expect to fare best. How they would have fared on another treatment modality is unknown. Controlling for case mix by accounting for patient differences in such factors as age, sex, race, and comorbidity provides an approximate means for overcoming this problem.

One final limitation of this study derives from the cross-sectional study design; that is, the individual patients were interviewed only once at approximately the same point in time. In contrast, a more expensive longitudinal design, collecting data at several points in time for each individual, would have permitted the analysis of other important questions. Most notably, questions of survival and treatment modality switching over time are impossible or at least difficult to address with a cross-sectional design. Nonetheless, this cross-sectional design can, with adequate controls for case mix, approximate the goal of case control studies such as those common in epidemiology (Kurland et al., 1970; MacMahon and Pugh, 1970; Ibrahim and Spitzer, 1979).

Conclusion

The sample design and survey methodology for the National Kidney Dialysis and Kidney Transplantation Study has been reviewed in detail in this chapter. Although a probability sample design perhaps would have been more desirable, the use of a purposive sample of 11 dialysis and transplant centers and a random probability sample of 859 dialysis and transplant patients reflects the fiscal constraints of the project. Although not ideal, it is important to note that this sample design represents a very significant improvement over the sample designs of past studies. This study design differs from past study designs in two important ways. First, past studies have, for the most part, been little more than single-center studies with convenience (i.e., nonrandom) samples of patients. Second, many earlier sample designs have failed to include patients on all treatment modalities. Thus, the National Kidney Dialysis and Kidney Transplantation Study represents an attempt to overcome these deficiencies and to improve on past study designs.

Although it is inappropriate to generalize the study results to the population of all patients with end stage renal disease (ESRD) a great deal can be learned about the relationship between treatment modality and the quality of life, level of disability, extent of rehabilitation, and quality of care of ESRD patients. In this regard, the strengths and weaknesses of the sample design are similar to those of population-based epidemiological studies such as the Framingham Heart Study (Dawber, 1980). On the one hand, the participants in the study are nonprobability sample taken from the population of the United States and, consequently, constraints are imposed on statistical inference. Yet, on the other hand, the sample selected does facilitate the understanding of complex relationships among a set of variables that are key to particular phenomena under study. In the case of the Framingham Heart study, the concern is with the epidemiology of cardiovascular disease, but in the National Kidney Dialysis and Kidney Transplantation Study the concern is with how various treatment modalities affect patient outcomes.

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Chapter 4.
Demographic comparison

Introduction

As described in Chapter 3, the sample for the National Kidney Dialysis and Kidney Transplantation Study (NKDKTS) is nonrepresentative of the U.S. end stage renal disease patient population. This is not unusual—only one sample survey study of end stage renal disease (ESRD) patients has been representative of the universe from which the patients were drawn (Bryan et al., 1978). As a result, no attempt is made in this respect to infer the results of the NKDKTS to the population of patients without appropriate qualifications. The purpose of this chapter is to compare the demographic characteristics of the NKDKTS sample with the general Medicare ESRD patient population. It is noteworthy, however, that this comparison is problematic for several reasons. First and foremost, as noted above, the NKDKTS sample is not a national probability sample; rather it is a purposive sample of 11 selected centers with patients stratified by treatment modality. Second, the best available demographic estimates for the ESRD population are for 1979; the NKDKTS survey was conducted from November 1981 through April 1982. Third, the NKDKTS sample of transplants includes transplant patients who were Medicare eligible at the time of the study as well as those whose eligibility had expired (Medicare eligibility expires 3 years post-transplant). There are other problems as well, including the definition of modalities and missing information.

Despite the foregoing problems, and with appropriate precautions, the NKDKTS sample data can provide useful insights about the general ESRD population. Assuming, for example, that the 11 centers are not totally atypical of the general ESRD population, inferences drawn about the relationships among treatment modality, the characteristics of patients, and outcomes have some validity for the entire population. Nonetheless, great caution must be exercised in making such generalizations. In spite of apparent problems, policy decisions concerning both coverage and research are made on the basis of whatever information is available. The aim here is to provide some guidance in the reliability of differing types of generalizations from the NKDKTS data.

General comparisons

The survey methodology and sample design of the National Kidney Dialysis and Kidney Transplantation Study (NKDKTS) have been described in detail in Chapter 3 of this report. In this chapter, the NKDKTS sample is compared at a general level with the entire population with end stage renal disease (ESRD) and, in addition, demographic comparisons are made within modality (i.e., intramodality). In some studies, the inclusion of patients who are not Medicare eligible can be problematic. The NKDKTS sample did not differentiate in selection between those patients eligible for Medicare and those who were not eligible. Liu (1982) estimates that 93 percent of those patients receiving dialysis in the United States are eligible for Medicare. In the NKDKTS sample, 7.7 percent of all the patients said they did not qualify for Medicare benefits.

Although the overall percentages for the sample are similar to those for the population, this is slightly misleading. First, the NKDKTS sample includes transplant patients whose Medicare eligibility had expired (38.8 percent of these patients were not eligible). In fact, only 1.6 percent of the dialysis patients said they did not qualify for Medicare coverage, so the sample may underrepresent non-Medicare dialysis patients.

The population estimates available for comparison with the sample also suffer from a number of limitations. The available population data come from two sources, both collected by the Health Care Financing Administration (HCFA). First, there is HCFA's Facility Survey, an annual (or sometimes biannual) census survey of all the facilities providing maintenance dialysis and the hospitals performing transplants. During this census dialysis facilities are asked for the number of patients by modality who were undergoing dialysis treatment as of the last day of the year. The transplant centers are asked how many transplants were performed in the past year. Generally, the census does not make a distinction between Medicare and non-Medicare patients. These figures are then published according to each ESRD Network in the ESRD Annual Report to Congress. The second data source is the Medicare claims data. HCFA staff have created and analyzed a file of all claims through 1979 (P. Eggers, personal communication). Special unpublished tabulations from their analysis of the 1979 data have been used in this chapter. These tabulations have the virtue of providing the best available estimates of the age, sex, and race composition (by modality) of the Medicare population.[1] Besides being somewhat dated, these data are also limited because only 47.6 percent of the 51,530 patients on file had an identifiable modality. Also, only the Medicare-eligible patients are listed. As suggested above, the latter creates special problems for transplant patient comparisons.[2]

The 1981 estimates of the number of patients on each modality are based on the Facility Survey data and shown in Table 4-1. It is obvious from the data in Table 4-1 that the NKDKTS sample (stratified by modality) is not representative (at an aggregate level) of the entire population. Thus, simple descriptive statistics based on the entire sample (without distinctions among modalities) are unlikely to be good estimates for the entire population. For those characteristics that vary by

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[1] In principle, a more recent tabulation could be made using the ESRD Medical Information System. However, the quality of the information about current modality in that file is problematic.

[2] These tabulations on the HCFA's Medicare reimbursement files show that 24.2 percent of those with an identifiable modality in 1979 were those with transplants.

Table 4-1

Number and percent of patients with end stage renal disease and those in the National Kidney Dialysis and Kidney Transplantation Study sample, by treatment modality

Modality	ESRD population[1] Number	ESRD population[1] Percent	NKDKTS sample Number	NKDKTS sample Percent
Dialysis				
Total	58,770	79.6	715	83.2
In-center	49,312	66.8	347	40.4
Home hemodialysis	4,480	6.1	287	33.4
Continuous peritoneal dialysis	4,333	5.9	81	9.4
Home peritoneal	645	.9	0	0.0
Transplant				
Total	73,870	100.0	859	100.0
1981 new transplants[2]	4,883	—	—	—
Transplants on Medicare	7,700	—	—	—
Transplants ever covered under Medicare[3]	14,200	—	—	—
All functioning transplants[3]	15,000	20.5	144	16.8

[1] Dialysis and new transplant estimates are based on the Annual Facility Survey reported in 1982 ESRD Annual Report to Congress.

[2] Only those performed in 1981, not those with functioning grafts in 1981.

[3] These figures are estimates (Krakauer, 1983) derived from what is known about the survival of transplants and the number done each year. Krakauer estimates that 14,200 functioning transplants were ever covered under the Medicare program as of December 1981. The 15,000 represents this estimate inflated by 7 percent to reflect non-Medicare living transplants.

NOTES: ESRD is end stage renal disease. NKDKTS is the National Kidney Dialysis and Kidney Transplantation Study.

Table 4-2

Number and percent distribution of persons in the National Kidney Dialysis and Kidney Transplantation Study sample and percent distribution of the end stage renal disease population and of the 1979 U.S. population, by census region and site

Census region and site	NKDKTS sample Number	NKDKTS sample Percent distribution	Percent distribution of ESRD population[1] 1979 Medicare	Percent distribution of ESRD population[1] 1981 report	Percent distribution of 1979 U.S. population
Total	859	100.0	100.0	100.0	100.0
Northeast	178	20.7	24.9	22.8	22.3
Eastern Maine Hospital	9	—	—	—	—
The Kidney Center	105	—	—	—	—
Downstate Medical Center	64	—	—	—	—
North Central	109	12.7	22.0	24.1	26.5
Indiana University	77	—	—	—	—
Bishop-Clarkson	32	—	—	—	—
South	307	35.7	33.8	34.6	32.5
Nalle Clinic	77	—	—	—	—
Dallas Kidney Center	179	—	—	—	—
Dialysis Clinics, Inc.	51	—	—	—	—
West	265	30.9	19.3	18.5	18.7
Northwest Kidney Center	221	—	—	—	—
West Contra Costa	10	—	—	—	—
Presbyterian	34	—	—	—	—

[1] The 1979 estimates come from unpublished State tabulations by HCFA and include only the Medicare-eligible patients. The 1981 estimates come from the Annual Facility Survey and cover non-Medicare patients as well, but include only those transplanted in 1981. The U.S. population estimates are from the U.S. Bureau of the Census, Statistical Abstract of the United States, 1980.

NOTES: NKDKTS is the National Kidney Dialysis and Kidney Transplantation Study. ESRD is end stage renal disease.

modality, weighting by modality would have to be used to develop an aggregate estimate for the entire population. Thus, it is inappropriate to generalize the results based on the NKDKTS sample to the entire ESRD population without adjusting for modality (except, of course, when estimates do not vary by modality). Furthermore, because most analyses of the NKDKTS data present estimates for the sample according to treatment modality, for purposes of generalization to the entire population, it is important to keep in mind that two-thirds of the ESRD population is on in-center hemodialysis.

Before turning to intramodality characteristics, it is instructive to consider one further aggregate comparison—regional representation. A general comparison of the sample (ignoring modality), the ESRD Medicare population, and the U.S. population is made in Table 4-2. The ESRD figures are for 1979, and they are taken from the unpublished tabulations cited earlier. Clearly, in the aggregate, the sample significantly overrepresents the West Region and underrepresents the North Central Region. Of course, these differences do not necessarily imply that particular modalities are not evenly distributed regionally, though, as is described later, this is the case. The other two columns in Table 4-2 illustrate the well-known variation (Relman, 1980; Eggers, 1984) in the prevalence of ESRD treatment among States. The North Central Region has a much lower prevalence than would be expected on the basis of population alone. The other three regions, and most particularly the Northeast, have higher than expected rates. The determinants of this variation among States is the subject of continuing research, but, in any case, the NKDKTS sample is not, and was not intended to be, directly representative of the various regions of the country. Although there are significant numbers in the sample from each region, weighting would be required to develop aggregate estimates of those characteristics that were thought to vary by region.

Intramodality comparisons

Tables 4-3 through 4-5 show intramodality demographic (age-sex-race) comparisons for in-center hemodialysis, home hemodialysis, and transplant patients, respectively. Again, these comparisons are problematic for several reasons. First, the available population estimates are for 1979 and come from special, unpublished tabulations on Medicare's reimbursement files. Thus, only Medicare recipients are included. This could be a problem for comparisons involving transplant patients. Also, although few patients on continuous peritoneal dialysis (CPD) were in the home population in 1979, comparisons can be made for home hemodialysis, but no comparison can be made for the CPD sample. Another problem, as noted above, is that these population estimates are based on a subset (47.6 percent) of Medicare-eligible patients whose modality could be identified. A bias may exist if the identification of modality should happen to be related to age, sex, or race. Even though such a bias has not been found, it is assumed that this subset of patients is similar to that of the entire population with end stage renal disease (ESRD), both Medicare and non-Medicare.

Table 4-3 shows the comparisons for in-center hemodialysis patients by race (white and black), sex, and four broad age categories. Other racial groups are not included in these comparisons because their numbers in the sample are too small for meaningful comparison. It is well-known that renal failure is more prevalent among black persons than among white persons. Therefore, the fact that they comprise 32 percent (not shown explicitly in the table) of the ESRD in-center population is not surprising. However, 43.9 percent of the NKDKTS in-center sample is black; thus, white persons are most likely underrepresented relative to their proportion in the ESRD in-center population. The race composition of the sample is significantly different from that of the in-center ESRD population (chi-square = 20.1, significant at the .5-percent level). The sex composition appears roughly correct for white persons, but black females were oversampled slightly. (In neither case is the difference significant at the .5-percent level.) Looking at the age comparisons within race-sex groups, no clear pattern emerges though there are some apparently large differences for particular race-sex-age categories. (Recall, in addition, that the sample includes no one under 18 years of age.) In fact, none of the chi-square values for age differences are statistically significant. One gains a general impression that adjustments or controls for race are particularly important in generalizing from this in-center sample and that sex and age adjustments must be considered for particular subgroups.

The same comparison for home hemodialysis patients is shown in Table 4-4. Black patients constitute 20.1 percent of the ESRD population, but constitute only 9.0 percent of the NKDKTS sample. Thus, this particular subsample underrepresents black persons in the ESRD home population (chi-square = 19.4, significant at .5-percent level). In fact, the number of black persons in the sample is too small to permit meaningful comparison

Table 4-3

Percent distribution of in-center hemodialysis patients in the 1979 Medicare end stage renal disease (ESRD) population and number and percent distribution of those in the National Kidney Dialysis and Kidney Transplantation Study (NKDKTS) sample, by race, sex, and age

Race, sex, and age	Percent distribution of 1979 Medicare ESRD population[1]	NKDKTS sample	
		Percent distribution	Number
White male			
Total	100.0	100.0	98
Under 24 years	6.3	7.1	7
25-44 years	24.1	18.4	18
45-64 years	41.3	43.9	43
65 years or over	28.3	30.6	30
Chi-square = 1.737			
White female			
Total	100.0	100.0	85
Under 24 years	7.5	4.7	4
25-44 years	20.4	21.1	18
45-64 years	44.7	55.3	47
65 years or over	27.3	18.8	16
Chi-square = 5.200			
Black male			
Total	100.0	100.0	64
Under 24 years	4.8	0.0	0
25-44 years	31.1	39.1	25
45-64 years	46.1	45.3	29
65 years or over	18.0	15.6	10
Chi-square = 4.544			
Black female			
Total	100.0	100.0	79
Under 24 years	3.5	2.5	2
25-44 years	21.2	30.4	24
45-64 years	49.8	48.1	38
65 years or over	25.6	19.0	15
Chi-square = 4.504			
Other			
Total	0.0	100.0	18

[1] These estimates are based on special, unpublished tabulations by the Health Care Financing Administration and are expressed as renal-person years.

NOTES: None of the chi-squares shown were significant. Percents may not sum to 100.0 because of rounding error. Numbers of incenter hemodialysis patients in the 1979 Medicare ESRD population were white males, 5,561; white females, 4,536; black males, 2,477; and black females, 2,302. ESRD is end stage renal disease, and NKDKTS is the National Kidney Dialysis and Kidney Transplantation Study.

Table 4-4

Percent distribution of home hemodialysis patients in the 1979 Medicare end stage renal disease (ESRD) population and number and percent distribution of those in the National Kidney Dialysis and Kidney Transplantation Study (NKDKTS) sample, by race, sex, and age

Race, sex, and age	Percent distribution of 1979 Medicare ESRD population[1]	NKDKTS sample	
		Percent distribution	Number
White male			
Total	100.0	100.0	156
Under 24 years	6.6	3.9	6
25-44 years	36.7	41.0	64
45-64 years	45.2	42.3	66
65 years or over	11.6	12.8	20
Chi-square = 2.862			
White female			
Total	100.0	100.0	87
Under 24 years	6.7	5.8	5
25-44 years	31.3	36.8	32
45-64 years	51.1	51.7	45
65 years or over	10.9	5.8	5
Chi-square = 2.844			
Black male			
Total	100.0	100.0	16
Under 24 years	3.4	0.0	0
25-44 years	43.8	62.5	10
45-64 years	46.5	31.3	5
65 years or over	6.3	6.3	1
Chi-square = 2.528			
Black female			
Total	100.0	100.0	8
Under 24 years	4.9	0.0	0
25-44 years	46.2	37.5	3
45-64 years	44.3	62.5	5
65 years or over	4.7	0.0	0
Chi-square = 1.454			
Other			
Total	0.0	100.0	13

[1] These estimates are based on special unpublished tabulations by the Health Care Financing Administration and are expressed as renal-person years.

NOTES: None of the chi-squares shown were significant. Percents may not sum to 100.0 because of rounding error. Numbers of home hemodialysis patients in the 1979 Medicare ESRD population were white males, 1,386.5; white females, 839.8; black males, 358.6; black females, 201.3. ESRD is end stage renal disease; and NKDKTS is the National Kidney Dialysis and Kidney Transplantation Study.

by sex and age. The white subgroups appear to have a roughly appropriate distribution by sex, accompanied by some rather minor differences by age category. In neither case are the differences statistically significant. As with the in-center sample, race and sex adjustments are likely to be more important than age adjustments. Unfortunately, the small number of black persons in the home hemodialysis sample makes any generalization somewhat difficult.

The comparison for transplant recipients are shown in Table 4-5. It should be recalled that the NKDKTS covers all patients with functioning grafts, and that the Medicare figures reflect only those eligible for Medicare in 1979. Transplants were only covered under Medicare for a period of 1 year post-transplant through October 1978, and after that the period of eligibility was extended to 3 years. For those in the NKDKTS, only 61.2 percent of the patients reported themselves as qualifying for Medicare benefits. Ignoring these incompatibilities, of the patients in the NKDKTS and ESRD program, 12 percent and 17 percent, respectively, were black (this difference is not statistically significant). The small percent of blacks makes age-sex comparisons meaningless for this modality. For white patients, the proportion of females (41 percent) is similar to that in the sample (44 percent), but this difference is not statistically significant. The age distribution of the sample of white patients contains a greater proportion of those over 65 years of age than the population does, and the differences are statistically significant for both. This could reflect both changes in the delivery of ESRD services between 1979 and 1982 and a possible selection bias inherent in keeping long-term transplant survivors in the NKDKTS but not in the ESRD program.

It was shown above that the NKDKTS sample tended to overrepresent the West Region and underrepresent the North Central Region at the aggregate level. The same comparison within modality but using only the 1981 population estimated from the Annual Facility Survey is shown in Table 4-6. The in-center sample shows that the regional representation in the sample is biased, with a significant underrepresentation of the North Central Region and overrepresentation of the South and West. For the home hemodialysis sample, the North Central and South Regions are underrepresented, the West is greatly overrepresented, and the Northeast is somewhat overrepresented. As a group, these differences are statistically significant. CPD patients are greatly underrepresented in the Northeast and overrepresented in the South. Again, these differences are statistically significant. The transplant comparison reflects only the volume of transplants in 1981 reported by the ESRD Networks. The percentages in the table reveal that the difference between the sample and the population in terms of transplants performed is not statistically significant. However, there appears to be a tendency for the South to be overrepresented and the North Central Region to be underrepresented.

Table 4-5

Percent distribution of transplant patients in the 1979 Medicare end stage renal disease (ESRD) population and number and percent distribution of those in the National Kidney Dialysis and Kidney Transplantation Study (NKDKTS), by race, sex, and age

Race, sex, and age	Percent distribution of 1979 Medicare ESRD population[1]	NKDKTS sample Percent distribution	NKDKTS sample Number
White male			
Total	100.0	100.0	68
Under 24 years	21.4	13.2	9
25-44 years	51.6	60.3	41
45-64 years	26.2	20.6	14
65 years or over	0.8	5.9	4
Chi-square = 22.555***			
White female			
Total	100.0	100.0	54
Under 24 years	22.5	25.9	14
25-44 years	52.2	50.0	27
45-64 years	24.5	16.7	9
65 years or over	0.9	7.4	4
Chi-square = 22.216***			
Black male			
Total	100.0	100.0	12
Under 24 years	12.7	16.7	2
25-44 years	60.8	50.0	6
45-64 years	26.0	33.3	4
65 years or over	0.5	0.0	0
Chi-square = .668			
Black female			
Total	100.0	100.0	5
Under 24 years	18.0	0.0	0
25-44 years	49.7	60.0	3
45-64 years	32.3	40.0	2
65 years or over	0.0	0.0	0
Chi-square = 1.097			
Other			
Total	0.0	100.0	5

[1] These estimates are based on special, unpublished tabulations by the Health Care Financing Administration and are expressed as renal-person years.

NOTES: ***Statistically significant at the .005 level. Percents may not sum to 100.0 because of rounding error. Numbers of transplant patients in the 1979 Medicare ESRD population were white males, 2,703.1; white females, 1,936.2; black males, 635.1; and black females, 327.8. ESRD is end stage renal disease, and NKDKTS is the National Kidney Dialysis and Kidney Transplantation Study.

Table 4-6

Percent distribution of patients with end stage renal disease in the Annual Facility Survey and in the National Kidney Dialysis and Kidney Transplantation Study (NKDKTS) sample, by modality and region

Modality and region	Percent distribution of Annual Facility Survey[1]	Percent distribution of NKDKTS sample
In-center		
Total	100.0	100.0
Northeast	23.8	22.5
North Central	22.3	4.0
South	35.6	43.5
West	18.3	30.0
Chi-square = 83.475***		
Home hemodialysis		
Total	100.0	100.0
Northeast	21.3	26.1
North Central	27.3	12.2
South	28.8	20.6
West	22.6	41.1
Chi-square = 71.424***		
Continuous peritoneal dialysis		
Total	100.0	100.0
Northeast	17.9	2.5
North Central	29.6	24.7
South	35.6	51.9
West	16.8	21.0
Chi-square = 18.056***		
Transplants		
Total	100.0	100.0
Northeast	19.1	16.0
North Central	34.3	27.8
South	28.7	38.2
West	18.0	18.1
Chi-square = 6.806		

[1] There is some slight error in these aggregated estimates from the Annual Facility Survey because three networks cross regional boundaries. In those cases, the total was assigned to the region with the greatest population in the network.

NOTE: ***Significant at .005 level. Percents may not sum to 100.0 because of rounding error. The number of end-stage renal disease patients in the Annual Facility Survey and in the NKDKTS by modality are incenter, 48,604 and 347, respectively; home hemodialysis, 4,432 and 287, respectively; continuous peritoneal 4,293 and 81, respectively; and transplants, 4,817 and 144, respectively.

Summary and conclusion

This chapter provides descriptive comparisons between the demographic characteristics of the NKDKTS sample and the ESRD patient population. Given the data limitations, the accuracy of such comparisons is questionable. However, the following broad generalizations seem to be in order:

- Because of stratification and design considerations (viz., the inclusion of non-Medicare eligibles), the sample as a whole must be weighted by modality if general statements about the ESRD population are to be made. In accordance with the aims of the study, the home hemodialysis population was given a larger representation in the sample (approximately 6.4 percent of the ESRD population) than the other modalities (in-center = .7 percent; CPD = 1.9 percent, and transplant = 1.0 percent).
- At the aggregate level, the sample overrepresents the West Region and underrepresents the North Central Region. Also, although this same pattern held up for dialysis modalities but not for transplantation, the strength of the pattern varied by modality. In any case, there were significant intramodality differences.
- In general, the NKDKTS sample provides a fair representation of the age distribution within modalities.
- The in-center subsample appears to underrepresent whites, overrepresent black females, and to misrepresent slightly the age distribution for females, white and black.
- The home hemodialysis subsample appears to underrepresent black patients, but fairly represents the age-sex distribution of white patients. (There were too few black patients for meaningful age-sex comparisons.)
- The transplant subsample (with most severe data problems for the comparison population) may slightly underrepresent black patients and may overrepresent the aged (65+) in the Medicare program (but may accurately represent the aged in the whole transplant population).

These findings have several implications. First, it should be clear that implicit generalization (or more risky explicit extrapolation) based on descriptive statistics from the NKDKTS sample should take account of modality differences and probably demographic differences (whenever race, sex, or age are believed to be related to the variable in question). Second, because the regional distribution is not generally representative, care must be taken in estimating magnitudes of quantities like hospital length of stay, which varies significantly by region. Furthermore, this implies that intermodality multivariate analyses of the data would do well to control for region and demographic characteristics.

Although the results reported here are not profound, they do serve to provide a useful general description of the sample as well as to encourage appropriate caution in generalization from descriptive statistics of the sample. Only if the statistics of interest are shown not to vary by region, age, sex, or race can it be assumed that they are reasonably accurate descriptions of the ESRD population. In addition, given the small sample size in some of the race-sex-age cells by modality, any explicit extrapolation would be enhanced by some rate smoothing across cells prior to final computation. However, it cannot be overemphasized that although implicit generalization almost always takes place when the data are presented, explicit extrapolation (using post-stratification) may be seriously compromised by the selective sample design used in this study.

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Chapter 5.
Descriptive analysis of patients

Introduction

As described in previous chapters, considerable data were collected on the patients who participated in the National Kidney Dialysis and Kidney Transplantation Study (NKDKTS). The methods by which these data were obtained have been described in Chapter 3. The purpose of this chapter is to provide a broad descriptive overview of patients with end stage renal disease (ESRD) who participated in the study, highlighting major differences in the characteristics of these patients according to treatment modality (i.e., home hemodialysis, in-center hemodialysis, continuous peritoneal dialysis (CPD), and kidney transplantation). Some of these data are more thoroughly analyzed in subequent chapters.

The descriptive results presented in this chapter have been organized around several characteristics of the patients. These are as follows:

- Sociodemographic characteristics.
- Medical or clinical characteristics.
- Marital and family relationships.
- Personal adjustment.
- Perceived health status.
- Employment.

As the data permit, the results are presented for all ESRD patients as well as for each of the four treatment modalities. However, further stratification of the data to smaller and smaller subgroups of patients often results in rather small numbers of individuals in some cells. Thus, when a question is asked of a small subset of patients (for example, those currently employed), the data are not broken down by treatment modality and only aggregate data are presented.

Sociodemographic characteristics

Age

The age distribution of the patients with end stage renal disease (ESRD) who were included in the National Kidney Dialysis and Kidney Transplantation Study (NKDKTS) is presented in Table 5-1. The patient ages range from 18.03 to 85.05 years, with a mean age of 47.60 years. However, as can be seen from the table, there is considerable variation in the age distribution of patients on the different treatment modalities. Transplant patients are younger than all other patient groups, with a mean age of 37.15 years. In-center hemodialysis and patients on continuous peritoneal dialysis (CPD) are the oldest, with mean ages of 51.92 and 49.80, respectively.

Sex

The distribution of ESRD patients by sex also varies by treatment modality. As can be seen in Table 5-2, a larger proportion of males are on home hemodialysis compared with the proportion on in-center hemodialysis. However, for those on in-center hemodialysis, the patients are evenly divided between males and females. A slightly higher percent of females are on CPD than males, however, the reverse is true of transplant patients. Overall, 55.4 percent of the patients included in the study are male and 44.6 percent are female.

Race

The racial distribution of patients in the study is shown in Table 5-3. Overall, 72.6 percent of the patients are white, 23.0 percent are black, and 4.4 percent are of other races. Again, there is a significant difference in the racial composition of the four modality groups: Home hemodialysis patients and CPD and transplant patients are predominantly white, but those on in-center hemodialysis are predominantly black.

Education

Years of education completed by the ESRD patients included in the study are presented in Table 5-4. The average educational level, in terms of the mean number of school years completed, for all patients is 12.1 years. Home hemodialysis patients are clearly better educated (with a mean of 12.8 years of school completed) than those in other modality groups. In-center hemodialysis patients, with a mean of 11.5 years of school completed, are the least educated group. Differences are less dramatic for CPD and transplant patients.

Marital status

The current marital status of the ESRD patients included in the study is presented in Table 5-5. As can be seen from the table, the majority of patients are married; however, the percent varies by treatment modality. Not surprisingly, the home hemodialysis and the CPD groups that dialyze at home have the highest percents of married patients. The in-center hemodialysis group, in contrast, has the lowest percent of married patients. To a certain extent, these differences in marital status reflect the age differences of those in the modality groups. Transplant patients, being on the average younger than the other patient groups, have the highest percent of patients who have never married. Similarly, the in-center hemodialysis and CPD groups—the oldest

Table 5-1

Percent distribution of patients with end stage renal disease, by treatment modality and age, with mean and median age of patients in each modality

	Treatment modality				
Age	All modalities	Home hemodialysis	In-center hemodialysis	CPD	Transplant
			Percent distribution		
All ages	100.0	100.0	100.0	100.0	100.0
Under 20 years	1.3	0.3	0.9	0.0	4.9
20.00-24.99 years	4.9	3.5	3.2	2.5	13.2
25.00-29.99 years	8.1	8.7	6.1	7.4	11.8
30.00-34.99 years	9.6	10.1	7.8	8.6	13.2
35.00-39.00 years	9.7	13.2	6.4	6.2	12.5
40.00-44.99 years	9.9	9.4	6.7	11.1	18.1
45.00-49.99 years	10.9	10.5	9.0	12.3	15.3
50.00-54.99 years	10.9	9.4	13.9	12.3	5.6
55.00-59.99 years	11.9	15.3	11.6	16.0	3.5
60.00-64.99 years	9.7	9.8	13.0	8.6	2.1
65.00-69.99 years	7.4	6.3	11.3	7.4	0.0
70.00-74.99 years	3.7	2.8	5.5	6.2	0.0
75 years or over	2.2	0.7	4.6	1.2	0.0
			Age in years		
Mean	47.60	47.02	51.92	49.80	37.15
Median	47.55	46.34	53.64	51.08	38.54

NOTES: CPD is continuous peritoneal dialysis. Minimum age is 18.03. Maximum age is 85.05. Standard deviation is 14.64.

Table 5-2

Percent distribution of patients with end stage renal disease, by treatment modality and sex

	Treatment modality				
Sex	All modalities	Home hemodialysis	In-center hemodialysis	CPD	Transplant
			Percent distribution		
Both sexes	100.0	100.0	100.0	100.0	100.0
Male	55.4	64.1	50.0	45.7	56.3
Female	44.6	35.9	50.0	54.3	43.8

NOTE: CPD is continuous peritoneal dialysis.

Table 5-3

Percent distribution of patients with end stage renal disease, by treatment modality and race

	Treatment modality				
Race	All modalities	Home hemodialysis	In-center hemodialysis	CPD	Transplant
			Percent distribution		
All races	100.0	100.0	100.0	100.0	100.0
White	72.6	86.4	53.5	84.0	84.7
Black	23.0	8.7	42.5	9.9	11.8
Other	4.4	4.9	4.0	6.2	3.5

NOTE: CPD is continuous peritoneal dialysis.

Table 5-4

Percent distribution of patients with end stage renal disease, by treatment modality and years of education completed, with mean years completed by patients in each modality

Years of education	All modalities	Home hemodialysis	In-center hemodialysis	CPD	Transplant
			Percent distribution		
Total	100.0	100.0	100.0	100.0	100.0
Less than 8	14.3	10.5	18.8	14.8	11.2
9-12	46.4	42.0	47.2	51.9	50.3
13-16	30.6	33.2	29.6	24.7	30.8
17 or more	8.7	14.3	4.4	8.6	7.7
			Education completed		
Mean in years	12.1	12.8	11.5	11.9	12.2

NOTE: CPD is continuous peritoneal dialysis.

Table 5-5

Percent distribution of patients with end stage renal disease, by treatment modality and current marital status

Marital status	All modalities	Home hemodialysis	In-center hemodialysis	CPD	Transplant
			Percent distribution		
Total	100.0	100.0	100.0	100.0	100.0
Married	64.1	76.7	51.4	72.8	64.6
Widowed	6.8	3.5	11.6	9.9	0.0
Divorced	10.8	6.3	15.9	8.6	9.0
Separated	3.6	1.7	5.2	2.5	4.2
Never married	14.7	11.8	15.9	6.2	22.2

NOTE: CPD is continuous peritoneal dialysis

Table 5-6

Percent distribution of patients with end stage renal disease who have other individuals living in their households, by treatment modality and number of other individuals

Number of individuals	All modalities	Home hemodialysis	In-center hemodialysis	CPD	Transplant
			Percent distribution		
Total	100.0	100.0	100.0	100.0	100.0
None	14.1	9.8	20.8	10.0	9.0
1	36.1	38.3	36.5	45.0	25.7
2	20.3	19.9	16.7	26.2	26.4
3	15.5	19.2	12.3	13.7	16.7
4	7.4	5.2	7.6	2.5	13.9
5	3.5	4.9	2.3	0.0	5.6
6 or more	3.2	2.7	3.9	2.5	2.8
Mean number of people	1.92	1.99	1.77	1.64	2.30

NOTE: CPD is continuous peritoneal dialysis.

modality groups—have the highest percents of widowed patients. In-center hemodialysis patients have the highest percents of separated and divorced patients. The impact of the patient's kidney disease on marital relationships is discussed in a subsequent section of this chapter.

Household composition

The number of other individuals living in the ESRD patients household is summarized in Table 5-6. As can be seen from the table, approximately 90 percent of home hemodialysis, CPD, and transplant patients live with one or more other people. On the average, transplant patients and home hemodialysis patients tend to live with more people than in-center hemodialysis and CPD patients. Again, this may reflect the lower average age of these patients. A much higher percent of in-center hemodialysis patients live alone (20.8 percent).

Type of residence

The current type of residence of patients included in the study is presented in Table 5-7. Two-thirds (66.5 percent) of all ESRD patients live in owner-occupied single-family homes. The percent is highest among the home hemodialysis and CPD patient groups and lowest among the in-center hemodialysis group. The percents of patients living in both rented single-family homes and in rented units in multiple-family dwellings are highest for the in-center hemodialysis patient group.

Medical characteristics

Time since treatment began

All patients were asked when they began routine dialysis as a treatment for their kidney problem (or when they received their transplant, if they were transplanted prior to the onset of regular chronic maintenance dialysis). The length of time in years since patients with end stage renal disease (ESRD) who are included in the study began regular chronic maintenance dialysis is shown in Table 5-8. The mean length of time for all ESRD patients is 4.76 years, ranging from a low of 3.25 years for CPD patients to a high of 6.25 years for transplant patients. Home and in-center hemodialysis patients have means of 5.31 and 4.03 years, respectively.

Time on current treatment modality

The length of time in years since ESRD patients began their current treatment is shown in Table 5-9. All patients included in the study have been on their current modality an average of 3.35 years. However, length of time on current treatment modality varies considerably across the four modality groups. CPD patients have been on their current modality for the shortest time—an average of only .95 years. Transplant patients, on the other hand, have been on their current modality for an average of 4.28 years. Moreover, on the average, home hemodialysis patients have been on their current treatment modality longer than in-center hemodialysis patients.

Primary diagnosis

The primary kidney disease diagnoses for ESRD patients included in the study as reported on their medical records are shown in Table 5-10. The most commonly reported diagnosis for all modality groups is primary renal disease involving glomerular-arteriolar structures. This is the primary diagnosis in 41.1 percent of the cases. The next most commonly reported diagnoses are primary hypertensive renal disease (11.1 percent), interstitial disease (10.6 percent), polycystic kidney disease (10.0 percent), and diabetes

Table 5-7

Percent distribution of patients with end stage renal disease, by treatment modality and current type of residence

	Treatment modality				
Type of residence	All modalities	Home hemodialysis	In-center hemodialysis	CPD	Transplant
	Percent distribution				
Total	100.0	100.0	100.0	100.0	100.0
Single-family home (owned)	66.5	78.2	53.2	76.5	69.9
Single-family home (rented)	11.7	9.8	13.6	12.3	10.5
Unit in multiple-family dwelling (owned)	3.7	2.8	4.3	4.9	3.9
Unit in multiple-family dwelling (rented)	16.8	8.8	26.9	6.2	14.7
Nursing home or convalescent home	0.6	0.0	1.2	0.0	0.7
Other	0.6	0.4	0.9	0.0	0.7

NOTE: CPD is continuous peritoneal dialysis.

Table 5-8

Percent distribution of patients with end stage renal disease, by treatment modality and length of time since patients began regular chronic maintenance dialysis or received their transplants

	Treatment modality				
Length of time	All modalities	Home hemodialysis	In-center hemodialysis	CPD	Transplant
			Percent distribution		
Total	100.0	100.0	100.0	100.0	100.0
Less than 1 year	10.6	5.9	14.4	25.9	2.1
1.00 - 2.99 years	30.5	30.0	35.4	29.6	20.1
3.00 - 4.99 years	20.3	20.9	20.7	24.7	15.3
5.00 - 6.99 years	13.2	12.5	10.4	8.6	23.6
7.00 - 8.99 years	12.6	13.6	11.0	3.7	19.4
9.00 - 10.99 years	6.2	7.7	4.3	4.9	8.3
11.00 - 15.99 years	6.3	8.7	3.5	2.5	10.4
16 years or more	0.5	0.7	0.3	0.0	0.7
			Length of time		
Mean years	4.76	5.31	4.03	3.25	6.25
Median years	3.75	4.45	3.02	2.25	6.37

NOTES: Data for transplant patients are for those who were transplanted prior to the onset of regular chronic maintenance dialysis. CPD is continuous periotoneal dialysis. Minimum length of time was .21 years; maximum length of time was 20.77; and standard deviation was 3.56.

Table 5-9

Percent distribution of patients with end stage renal disease, by treatment modality and length of time on current modality, with mean and median years, by treatment modality

	Treatment modality				
Length of time	All modalities	Home hemodialysis	In-center hemodialysis	CPD	Transplant
			Percent distribution		
Total	100.0	100.0	100.0	100.0	100.0
Less than 1 year	23.3	20.9	19.7	54.3	19.4
1.00 - 1.99 years	19.0	16.7	18.5	37.0	14.6
2.00 - 2.99 years	14.6	15.7	17.3	7.4	9.7
3.00 - 3.99 years	9.2	8.0	11.8	0.0	10.4
4.00 - 4.99 years	8.5	10.1	11.0	1.2	3.5
5.00 - 5.99 years	5.2	4.2	6.1	0.0	8.3
6.00 - 6.99 years	4.0	2.8	4.3	0.0	7.6
7.00 - 7.99 years	4.2	4.5	3.2	0.0	8.3
8.00 - 8.99 years	4.3	4.5	4.3	0.0	6.3
9.00 - 9.99 years	2.9	5.2	0.9	0.0	4.9
10 years or more	6.9	7.3	2.9	0.0	6.9
			Length of time		
Mean years	3.35	3.81	3.14	0.95	4.28
Median years	2.08	2.50	2.30	0.83	3.50

NOTES: CPD is continuous peritoneal dialysis. Minimum length of time was .08 years; maximum length of time was 19.00 years; and standard deviation was 3.04.

Table 5-10

Percent distribution of patients with end stage renal disease, by treatment modality and primary kidney disease diagnosis

Primary diagnosis	Treatment modality All modalities	 Home hemodialysis	 In-center hemodialysis	 CPD	 Transplant
			Percent distribution		
All diagnoses	100.0	100.0	100.0	100.0	100.0
Interstitial disease	10.6	11.8	7.1	15.0	14.3
Polycystic kidney disease	10.0	15.0	8.0	10.0	5.0
Primary renal disease involving glomerular-arteriolar structures	41.1	45.0	35.9	30.0	52.1
Primary hypertensive renal disease	11.1	5.0	18.7	8.8	6.4
Nephrosclerosis	6.1	2.9	9.5	6.3	4.3
Systemic lupus erythematosis	1.6	1.8	1.2	2.5	1.4
Diabetes	9.7	8.2	10.1	16.2	7.9
Myeloma	0.4	0.0	0.9	0.0	0.0
Other	9.4	10.4	8.6	11.2	8.6

NOTE: CPD is continuous peritoneal dialysis.

Table 5-11

Percent of patients with end stage renal disease, by treatment modality and comorbid condition

Condition	Treatment modality All modalities	 Home hemodialysis	 In-center hemodialysis	 CPD	 Transplant
			Percent		
Angina, myocardial infarction	15.7	12.7	22.6	18.5	3.6
Other cardiovascular problem	23.4	23.6	32.3	18.5	4.3
Respiratory disease	8.6	4.6	14.7	8.6	2.2
Gastrointestinal problems	14.8	10.9	22.9	13.6	3.6
Neurological problems, cerebrovascular accident, including stroke	9.7	9.5	13.8	8.6	0.7
Musculoskeletal disorders, including bone disease	23.9	22.5	30.2	24.7	10.8
Infection other than access problems or peritonitis	4.0	2.8	6.2	2.5	2.2
Hepatitis	4.0	3.2	5.9	0.0	3.6
Hematologic problems other than anemia	3.3	2.5	5.6	1.2	0.7
Spinal abnormality (lower back problem, arthritis)	6.9	5.3	11.4	3.7	0.7
Average number of comorbid conditions	1.10	.98	1.55	1.00	.32

NOTES: Totals may be greater than 100.0 percent because patients may have more than one condition. CPD is continuous peritoneal dialysis.

(9.7 percent). There are differences in primary diagnosis by treatment modality, but given variation in diagnosis of renal disease by physicians, interpretation of these differences is difficult.

Comorbid conditions

Information regarding the prevalence and severity of comorbid conditions was abstracted from the medical records of patients with end stage renal disease. The percent of patients with various comorbid conditions is presented in Table 5-11. It is quite apparent that in-center hemodialysis patients were sicker than patients on other treatment modalities, both in terms of the prevalence of specific comorbid conditions and in terms of the average number of reported conditions. In-center hemodialysis patients were reported to have an average of 1.55 of the 10 comorbid conditions. Transplant patients were the least sick, having on the average only .32 comorbid conditions. Much less variation is observed among the in-center hemodialysis and CPD patient groups.

Table 5-12

Percent of patients with end stage renal disease, by past treatment modality and current treatment modality

	Past treatment modality								
Current patient treatment modality	Home hemodialysis	In-center hemodialysis	CPD	Transplant	Home intermittent peritoneal dialysis	In-center intermittent peritoneal dialysis	Mean number of different modalities	Percent on 3 or more modalities	Percent on 4 or more modalities
	Percent								
Home hemodialysis	100.0	71.2	1.8	19.6	0.7	4.2	2.0	18.2	1.4
In-center hemodialysis	8.1	100.0	2.9	13.3	1.7	6.4	1.3	5.8	0.6
CPD	35.0	55.0	100.0	17.5	3.8	15.0	2.3	38.8	12.5
Transplant	31.9	84.7	2.1	[1]100.0	2.8	11.1	2.3	29.9	3.5

[1] 13.9 percent of the current transplant patients had a previous failed transplant.

NOTE: CPD is continous peritoneal dialysis.

Table 5-13

Percent of patients with end stage renal disease, by treatment modality and symptoms experienced

	Treatment modality				
Symptom	All modalities	Home hemodialysis	In-center hemodialysis	CPD	Transplant
	Percent				
Pain	41.5	36.7	49.3	49.4	27.8
Tiring easily, no energy	64.5	67.1	67.3	81.5	43.1
Weakness, lack of strength	56.5	59.2	61.3	67.9	33.3
Aches, swelling, sick feeling	43.3	44.8	47.5	48.1	27.8
Fainting spells, dizziness	24.1	18.9	31.3	33.3	11.8
Nervousness, tension, anxiety	38.1	39.0	36.1	40.7	39.6
Shortness of breath, trouble breathing	31.3	31.7	37.3	34.6	14.0
Depression	29.3	25.4	31.8	37.0	26.4
Headaches	33.3	32.9	37.6	27.2	27.1
Cramping	41.8	42.0	52.3	43.2	15.3
Chest pains	19.9	18.2	25.1	17.5	11.8
Lower back pain	32.3	26.5	39.3	35.8	25.0
Swelling of body parts	23.9	20.4	25.7	34.6	20.8
Confusion	10.5	8.0	12.4	13.6	9.0
Difficulty sleeping	50.0	52.3	55.8	55.6	28.5
Gas pains	30.7	28.6	36.7	30.9	20.1

NOTE: CPD is continuous peritoneal dialysis.

Treatment modality experience

Patients were asked to provide information regarding their past experience with various treatment modalities. These results are reported in Table 5-12. As can be seen from the table, most patients have been on several treatment modalities. Transplant patients and those on continuous peritoneal dialysis (CPD) have been on the greatest number of different treatment modalities (an average of 2.3 each), and in-center hemodialysis patients have the least modality experience (1.3 modalities). For some end stage renal disease (ESRD) patients with blood access problems, CPD may be regarded as their sole dialysis option. This may account for the fact that 38.8 percent of CPD patients have been on three or more modalities, and 12.5 percent have been on four or more modalities. Among transplant patients, 29.9 percent have been on three or more modalities, but only 3.5 percent have been on four or more modalities.

It is also shown in Table 5-12 that the vast majority of all ESRD patients have been on in-center hemodialysis. This is not surprising, because in-center hemodialysis is often a patient's first treatment modality. However, few patients have had previous experience on CPD. Across all dialysis modalities, the percent of patients that have had a previous kidney transplant is similar—ranging from 13.3 percent of in-center hemodialysis patients to 19.6 percent of home hemodialysis patients.

Symptoms experienced by patients

All ESRD patients were read a list of symptoms and were asked whether or not each symptom had bothered

Table 5-14

Percent of hemodialysis patients, by treatment modality and symptoms experienced after finishing dialysis

Symptom	Total	Treatment modality Home hemodialysis	 In-center hemodialysis
		Percent	
Pain	11.3	8.5	13.7
Tiring easily, no energy	64.6	68.2	61.9
Weakness, lack of strength	68.5	68.2	69.2
Aches, swelling, sick feeling	19.5	16.1	22.4
Fainting spells, dizziness	32.0	31.5	32.6
Nervousness, tension, anxiety	19.7	18.2	20.9
Shortness of breath, trouble breathing	13.4	11.5	15.1
Depression	13.2	10.5	15.5
Headaches	36.2	39.5	33.7
Cramping	46.7	45.6	47.5
Chest pains	8.6	7.7	9.3
Lower back pain	15.7	12.9	18.0
Swelling of body parts	4.4	2.8	5.8
Confusion	9.4	9.4	9.3
Difficulty sleeping	32.2	31.2	33.2
Gas pains	18.5	16.8	20.1

them enough to be a problem in the last month. Patient responses to this question are summarized in Table 5-13. The most commonly reported symptoms include tiring easily or no energy, weakness or lack of strength, and difficulty sleeping. These symptoms were reported by over one-half of all patients included in the study. Other commonly reported symptoms include aches, swelling, or sick feeling; cramping; pain; nervousness, tension, or anxiety; and headaches. In general, in-center hemodialysis and CPD patients reported more symptoms than other patients, and with the exception of nervousness, tension, or anxiety, transplant patients experienced fewer symptoms than other modality groups. These differences, however, may be partially explained by the observed differences in the prevalence of comorbid conditions among the different modality groups.

Hemodialysis patients only were read the foregoing list of symptoms and were asked whether or not they have any of the symptoms just after they finish dialysis. These results are summarized in Table 5-14. The two most commonly reported symptoms, reported by approximately two-thirds of all hemodialysis patients, are tiring easily or no energy and weakness or lack of strength. Other symptoms which are frequently experienced following dialysis include cramping (46.7 percent), headaches (36.2 percent), difficulty sleeping (32.2 percent), and fainting spells or dizziness (32.0 percent).

Transplantation experience

Information regarding ESRD patients' transplantation experiences was obtained from the patients' medical records. Table 5-15 shows the number of kidney transplants as recorded on patient medical records. As can be seen from the table, less than 20 percent of home hemodialysis, in-center hemodialysis, and CPD patients previously have had a kidney transplant. Of those patients who have had a previous transplant, most have had only one. Although some patients have had two transplants, few have had three or four. Among transplant patients, 12.9 percent are reported to have had a previously failed graft.

The percent of ESRD patients included in the study who were on a waiting list for either a kidney from a living-related or a cadaveric donor (as recorded on their medical records) is shown in Table 5-16. Among home hemodialysis, in-center hemodialysis, and CPD patients, approximately 5 percent were awaiting a kidney from a living-related donor. There is little variation across the three treatment modality groups. Among these three groups, the percent of patients on a list awaiting a cadaveric kidney ranged from 18.2 percent for home hemodialysis patients to 10.3 percent for CPD patients. Among in-center hemodialysis patients, 15.3 percent were reported to be on a list awaiting a cadaveric kidney. It is, of course, possible that a particular patient could be awaiting a kidney from a living donor and also be on the waiting list for a cadaveric kidney.

Marital and family relationships

Previously it was shown that most end stage renal disease (ESRD) patients included in the study were married (Table 5-5) and that 85 percent of all patients lived in a household with one or more other persons (Table 5-6). Like any terminal or chronic disease, end stage renal disease can pose substantial problems for patients and their families. Thus, the patient interview contained a series of questions related to marital and family relationships, with several questions that focused on the impact of kidney disease and its treatment on these relationships.

Divorced and separated patients were asked if they thought that their kidney disease strained their marital relationship. Of the 124 separated and divorced patients, over one-third (37.4 percent) felt that their kidney disease strained their marriage. Similarly, of married patients who had not remarried since they got kidney disease, 35.5 percent felt that their kidney disease strained their current marital relationship. Interestingly, of those separated and divorced patients who felt that their kidney disease strained their marital relationship, 56.5 percent felt that their separation or divorce was a direct result of their kidney disease.

Married patients were asked how often they felt rejected by their spouse when they were sick. As can be seen from Table 5-17, 84.1 percent of all patients said they never felt rejected, 14.2 percent said they sometimes felt rejected, and only 1.7 percent said they often felt rejected. In general, ESRD patients are satisfied with their marriages, with 83 percent of married patients saying that they were either very satisfied or completely satisfied with their marriages (Table 5-18). Compared with the general population,

Table 5-15

Percent distribution of patients with end stage renal disease, who had kidney transplants, by treatment modality and number of transplants

Number of kidney transplants	All modalities	Home hemodialysis	In-center hemodialysis	CPD	Transplant
	Percent distribution				
All transplants	100.0	100.0	100.0	100.0	100.0
0	69.4	80.3	86.5	82.1	0.0
1	25.3	15.4	11.1	10.3	87.1
2	4.7	3.2	2.1	6.4	12.9
3	0.5	1.1	0.0	1.3	0.0
4	0.1	0.0	0.3	0.0	0.0

Treatment modality

NOTE: CPD is continuous peritoneal dialysis.

Table 5-16

Percent of patients with end stage renal disease on a waiting list for living-related and cadaveric kidneys, by treatment modality and type of donor

Type of donor	All modalities	Home hemodialysis	In-center hemodialysis	CPD	Transplant
	Percent				
Living-related donor	4.4	5.1	5.4	5.1	0.0
Cadaveric donor	13.2	18.2	15.3	10.3	0.0

Treatment modality

NOTES: Based on data recorded on patient's medical records. A patient may be on both lists. CPD is continuous peritoneal dialysis.

Table 5-17

Percent distribution of married patients with end stage renal disease, by treatment modality and frequency which patients feel rejected by their spouse when they are sick

Frequency	All modalities	Home hemodialysis	In-center hemodialysis	CPD	Transplant
	Percent distribution				
Total	100.0	100.0	100.0	100.0	100.0
Often	1.7	0.9	2.9	0.0	2.2
Sometimes	14.2	14.4	14.9	17.2	10.9
Never	84.1	84.7	82.3	82.8	87.0

Treatment modality

more ESRD patients said that they were completely satisfied with their marriages. However, more ESRD patients also said that they were completely dissatisfied with their marriages, compared with the general population.

Patients were asked several questions about their immediate family. As shown in Table 5-19, 58.7 percent of all ESRD patients felt that their immediate family was very close, and 31.6 percent felt that their family was pretty close. Only 7.0 percent and 2.6 percent of all patients felt that their immediate family was a little close or not at all close, respectively. Similarly, 59.6 percent of all patients said that their immediate family members get along together very well, and 34.4 percent said that they get along together pretty well at home (Table 5-20). Moreover, as can be seen from Table 5-21, most patients (77.5 percent) said that when a problem came up in the family, family members were very willing to help out.

When asked to compare their family with most other families, the majority of ESRD patients (58.3 percent) considered their own family to be about the same as other families (Table 5-22). However, 35.9 percent considered their family to be more happy than other families, and 5.8 percent considered their family to be less happy. Patients were asked whether they thought that their kidney disease in any way brought the family closer together or in any way drew the family apart. Responses to this question are summarized in Table 5-23. More than one-half of all patients felt that

Table 5-18

Percent distribution of married and separated patients with end stage renal disease, by treatment modality and level of satisfaction with marriage, and of the general population, by sex and level of satisfaction

Level of satisfaction	General population[1]		Treatment modality				
	Females	Males	All modalities	Home hemodialysis	In-center hemodialysis	CPD	Transplant
			Percent distribution				
Total	100.0	100.0	100.0	100.0	100.0	100.0	100.0
Completely satisfied	56.0	60.0	66.5	70.1	63.5	71.7	61.2
Very satisfied	23.0	27.0	16.5	17.2	12.7	15.0	23.5
Satisfied	8.0	6.0	5.5	4.1	7.4	3.3	6.1
Neutral	9.0	6.0	5.8	6.8	6.3	5.0	3.1
Dissatisfied	2.0	1.0	0.5	0.5	0.5	0.0	1.0
Very dissatisfied	1.0	—	0.7	0.5	1.6	0.0	0.0
Completely dissatisfied	1.0	0.0	4.4	0.9	7.9	5.0	5.1

[1] Campbell et al., 1976.
NOTE: CPD is continous peritoneal dialysis.

Table 5-19

Percent distribution of patients with end stage renal disease, by treatment modality and degree of closeness of immediate family

Degree of closeness	Treatment modality				
	All modalities	Home hemodialysis	In-center hemodialysis	CPD	Transplant
	Percent distribution				
Total	100.0	100.0	100.0	100.0	100.0
Very close	58.7	61.1	51.7	71.6	63.2
Pretty close	31.6	32.2	35.4	22.2	27.1
A little close	7.0	5.3	8.7	3.7	8.3
Not at all close	2.6	1.4	4.2	2.5	1.4

NOTE: CPD is continuous peritoneal dialysis.

Table 5-20

Percent distribution of patients with end stage renal disease, by treatment modality and how well family members get along together

How well	Treatment modality				
	All modalities	Home hemodialysis	In-center hemodialysis	CPD	Transplant
	Percent distribution				
Total	100.0	100.0	100.0	100.0	100.0
Very well	59.6	61.0	58.5	61.7	58.3
Pretty well	34.4	33.0	35.4	33.3	35.4
A little well	4.2	5.0	4.6	3.7	2.1
Not at all well	1.8	1.1	1.5	1.2	4.2

NOTE: CPD is continuous peritoneal dialysis.

Table 5-21

Percent distribution of patients with end stage renal disease, by treatment modality and willingness of family members to help out when problems arise

Level of willingness	All modalities	Home hemodialysis	In-center hemodialysis	CPD	Transplant
	Percent distribution				
Total	100.0	100.0	100.0	100.0	100.0
Very willing	77.5	80.8	71.5	84.0	81.3
Somewhat willing	16.4	15.7	18.5	14.8	13.9
A little willing	3.6	2.8	5.5	0.0	2.8
Not at all willing	2.5	0.7	4.5	1.2	2.1

NOTE: CPD is continuous peritoneal dialysis.

Table 5-22

Percent distribution of patients with end stage renal disease, by treatment modality and level of happiness of their family compared with most families

Level of happiness	All modalities	Home hemodialysis	In-center hemodialysis	CPD	Transplant
	Percent distribution				
Total	100.0	100.0	100.0	100.0	100.0
More happy	35.9	37.5	34.5	32.5	38.0
Less happy	5.8	5.8	5.6	6.3	5.6
About the same	58.3	56.7	59.9	61.2	56.3

NOTE: CPD is continuous peritoneal dialysis.

Table 5-23

Percent distribution of patients with end stage renal disease, by treatment modality and impact of kidney disease on the family

Type of impact	All modalities	Home hemodialysis	In-center hemodialysis	CPD	Transplant
	Percent distribution				
Total	100.0	100.0	100.0	100.0	100.0
Brought family closer together	58.5	61.7	47.4	67.5	73.4
Drew family apart	7.3	8.5	7.6	2.5	7.0
Neither	33.3	29.8	42.6	30.0	19.6
No family	0.9	0.0	2.4	0.0	0.0

NOTE: CPD is continuous peritoneal dialysis.

their kidney disease brought the family closer together, and only 7.3 percent felt that it drew the family apart. A large number, however, felt that it had no effect. In terms of their satisfaction with their family life, 65.8 percent of all patients said that they were either completely satisfied or very satisfied with the time they spend and the things they do with members of their family (Table 5-24). When compared with the general population, the percent of ESRD patients who were completely satisfied is approximately the same. However, the percent of ESRD patients who were not satisfied (neutral to completely dissatisfied) with their family life is higher than the comparable percent for the general population.

Finally, patients were asked a series of questions in an effort to determine the extent to which young children of ESRD patients have problems adjusting to their parents kidney treatment. A total of 344 patients report that they had children who were under 18 years of age when they began kidney treatment. Of these, 60 patients (17.4 percent) report that their children had problems adjusting to their treatment. Of these 60 patients, 17.5 percent say

Table 5-24

Percent distribution of patients with end stage renal disease, by treatment modality and level of satisfaction with family life, and of general population, by sex and level of satisfaction

Level of satisfaction	General population[1]		Treatment modality				
	Women	Men	All modalities	Home hemodialysis	In-center hemodialysis	CPD	Transplant
	Percent distribution						
Total	100.0	100.0	100.0	100.0	100.0	100.0	100.0
Completely satisfied	44.0	43.0	43.7	43.4	44.0	50.6	39.9
Very satisfied	28.0	31.0	22.1	26.6	17.6	24.7	22.4
Satisfied	14.0	13.0	13.3	13.3	13.8	8.6	14.7
Neutral	7.0	7.0	10.5	8.4	10.9	12.3	12.6
Dissatisfied	4.0	3.0	4.6	4.2	5.3	1.2	5.6
Very dissatisfied	3.0	2.0	2.9	2.1	3.5	2.5	3.5
Completely dissatisfied	1.0	1.0	2.9	2.1	5.0	0.0	1.4

[1] Campbell et al., 1976.

NOTE: CPD is continuous peritoneal dialysis.

Table 5-25

Percent distribution of patients with end stage renal disease, by treatment modality and frequency with which they get together with friends or relatives over a year's time

Frequency	Treatment modality				
	All modalities	Home hemodialysis	In-center hemodialysis	CPD	Transplant
	Percent distribution				
Total	100.0	100.0	100.0	100.0	100.0
Every day	3.6	1.4	5.2	2.5	4.9
Several days a week	17.0	17.9	12.8	18.8	24.3
About once a week	26.1	23.5	25.5	31.3	26.4
2 or 3 times a week	20.3	24.2	17.7	18.8	19.4
About once a month	11.5	13.7	10.1	15.0	8.3
5 to 10 times a year	8.7	9.1	9.9	3.7	7.6
Less than 5 times a year	12.9	8.4	18.8	10.0	9.0

NOTE: CPD is continuous peritoneal dialysis.

Table 5-26

Percent distribution of patients with end stage renal disease, by treatment modality and frequency with which they had friends over to their home during a 1-month period

Frequency	Treatment modality				
	All modalities	Home hemodialysis	In-center hemodialysis	CPD	Transplant
	Percent distribution				
Total	100.0	100.0	100.0	100.0	100.0
Every day	4.1	2.4	5.2	3.7	4.9
Several days a week	12.6	12.2	11.9	14.8	13.9
About once a week	18.5	19.9	15.7	22.2	20.1
2 or 3 times in past month	28.5	31.0	25.9	29.6	29.2
Once in past month	13.4	15.0	12.8	12.3	12.5
Not at all in past month	22.9	19.5	28.5	17.3	19.4

NOTE: CPD is continuous peritoneal dialysis.

that the problems were very serious, 40.4 percent say that they were moderately serious, 26.3 percent say that they were somewhat serious, and 15.8 percent say that the problems were not at all serious. Most (87.9 percent of those who initially had problems) feel that their children have now adjusted to their kidney treatment.

Social relationships

All patients were asked a series of questions concerning their social activities. Patients were asked, ''Over a year's time, about how often do you get together with friends or relatives, like going out together or visiting in each other's homes?'' As can be seen in Table 5-25, over three-quarters (78.5 percent) of all patients got together with friends or relatives at least once a month, and almost one-half (46.7 percent) saw friends or relatives one or more times a week.

A summarization of how often patients participated in a variety of activities in a 1-month period, including having friends over, visiting friends in their homes, talking with close friends or relatives on the phone, and writing a letter to a friend or relative is given in Tables 5-26 through 5-29. In general, patients with end stage renal disease (ESRD) entertained friends at home (Table 5-26) more often than they visited friends in their homes (Table 5-27). The majority of patients talked with friends or relatives on the telephone (Table 5-28) either every day (38.9 percent) or several days a week (26.2 percent). Few patients, on the other hand, wrote letters to friends or relatives (Table 5-29). Over two-thirds of all patients (68.8 percent) had not written a letter during the past month.

Finally, patients were asked to rate their friendships—the time spent with friends, the things they did together, the number of friends they had, as well as the particular people who were their friends. As can be seen from Table 5-30, most patients were satisfied with their friendships. Overall, 38.9 percent said that they were completely satisfied, and 19.5 percent said that they were very satisfied with their friendships. On the other hand, 16.1 percent were neutral, and 13.4 percent were either dissatisfied, very dissatisifed, or completely dissatisfied with their friendships.

Personal adjustment

Although the quality of life of patients with end stage renal disease (ESRD) is the subject of extensive analysis

Table 5-27

Percent distribution of patients with end stage renal disease, by treatment modality and frequency with which they visited friends in their homes during a 1-month period

Frequency	Treatment modality All modalities	Home hemodialysis	In-center hemodialysis	CPD	Transplant
	Percent distribution				
Total	100.0	100.0	100.0	100.0	100.0
Every day	0.8	1.0	0.6	1.2	0.7
Several days a week	9.6	6.3	11.3	9.9	11.8
About once a week	17.7	18.1	15.4	16.0	23.6
2 or 3 times in past month	23.8	28.2	18.6	23.5	27.8
Once in past month	18.3	20.9	15.4	19.8	19.4
Not at all in past month	29.8	25.4	38.8	29.6	16.7

NOTE: CPD is continuous peritoneal dialysis.

Table 5-28

Percent distribution of patients with end stage renal disease, by treatment modality and frequency with which they talked with close friends or relatives on the telephone during a 1-month period

Frequency	Treatment modality All modalities	Home hemodialysis	In-center hemodialysis	CPD	Transplant
	Percent distribution				
Total	100.0	100.0	100.0	100.0	100.0
Every day	38.9	34.9	40.1	43.2	41.5
Several days a week	26.2	29.2	24.4	22.2	26.8
About once a week	13.4	15.1	11.6	18.5	11.3
2 or 3 times in past month	9.9	10.2	8.7	9.9	12.0
Once in past month	4.6	4.9	4.4	3.7	4.9
Not at all in past month	7.1	5.6	10.8	2.5	3.5

NOTE: CPD is continuous peritoneal dialysis.

Table 5-29

Percent distribution of patients with end stage renal disease, by treatment modality and frequency with which they wrote a letter to a friend or relative during a 1-month period

	Treatment modality				
Frequency	All modalities	Home hemodialysis	In-center hemodialysis	CPD	Transplant
			Percent distribution		
Total	100.0	100.0	100.0	100.0	100.0
Every day	0.1	0.0	0.0	0.0	0.7
Several days a week	3.2	2.8	3.8	4.9	1.4
About once a week	6.5	7.7	4.1	8.6	9.0
2 or 3 times in past month	9.0	9.8	9.0	6.2	9.0
Once in past month	12.4	13.6	9.3	18.5	13.9
Not at all in past month	68.8	66.2	73.8	61.7	66.0

NOTE: CPD is continuous peritoneal dialysis.

Table 5-30

Percent distribution of patients with end stage renal disease, by treatment modality and level of satisfaction with their friendships

	Treatment modality				
Level of satisfaction	All modalities	Home hemodialysis	In-center hemodialysis	CPD	Transplant
			Percent distribution		
Total	100.0	100.0	100.0	100.0	100.0
Completely satisfied	38.9	40.6	38.8	37.0	36.8
Very satisfied	19.5	20.6	16.2	23.5	22.9
Satisfied	12.0	11.5	10.9	13.6	14.6
Neutral	16.1	15.4	18.5	13.6	13.2
Dissatisfied	4.9	5.9	5.3	3.7	2.8
Very dissatisfied	4.2	2.8	5.0	4.9	4.9
Completely dissatisfied	4.3	3.1	5.3	3.7	4.9

NOTE: CPD is continuous peritoneal dialysis.

Table 5-31

Percent distribution of patients with end stage renal disease, by treatment modality and how well they think they have adjusted to their dialysis treatments or their kidney transplant

	Treatment modality				
Level of adjustment	All modalities	Home hemodialysis	In-center hemodialysis	CPD	Transplant
			Percent distribution		
Total	100.0	100.0	100.0	100.0	100.0
Very well	66.7	69.0	57.8	67.9	82.6
Fairly well	29.1	27.5	35.8	30.9	15.3
Not too well	2.8	1.4	4.9	0.0	2.1
Fairly poorly	0.6	0.7	0.6	1.2	0.0
Very poorly	0.8	1.4	0.9	0.0	0.0

NOTE: CPD is continuous peritoneal dialysis.

in Chapter 6, this section examines several questions that focus on the overall level of happiness of ESRD patients and on how well patients have adjusted to their kidney treatment. The majority of ESRD patients felt that they had adjusted well to their kidney treatment. As can be seen in Table 5-31, 66.7 percent felt that they had adjusted very well, and 29.1 percent felt that they had adjusted fairly well to their treatment. Only 4.2 percent feel that they have adjusted not too well, fairly poorly, or very poorly.

Dependence on others can be a serious problem among patients with chronic medical conditions. ESRD patients were asked how independent they feel they are managing their own lives. Overall, 38.9 percent said they were very independent, and 50.2 percent said they were pretty independent in managing their own lives (Table 5-32). The percent of patients responding very independent was higher among transplant and in-center hemodialysis patients, compared with home hemodialysis and CPD patients.

Patients were also asked to what extent their dependence on others had been a problem since they had been ill with kidney disease. Only 8.2 percent felt that their dependence has been a great problem (Table 5-33).

Table 5-32

Percent distribution of patients with end stage renal disease, by treatment modality and their level of independence in managing their own lives

	Treatment modality				
Level of independency	All modalities	Home hemodialysis	In-center hemodialysis	CPD	Transplant
			Percent distribution		
Total	100.0	100.0	100.0	100.0	100.0
Very independent	38.9	34.7	42.9	27.2	44.4
Pretty independent	50.2	56.5	43.5	58.0	49.3
Not very independent	8.0	7.0	9.6	9.9	4.9
Not at all independent	2.9	1.8	4.1	4.9	1.4

NOTE: CPD is continuous peritoneal dialysis.

Table 5-33

Percent distribution of patients with end stage renal disease, by treatment modality and whether their dependence on others is a problem

	Treatment modality				
Significance of dependence	All modalities	Home hemodialysis	In-center hemodialysis	CPD	Transplant
			Percent distribution		
Total	100.0	100.0	100.0	100.0	100.0
A great problem	8.2	9.2	9.6	3.7	5.6
Somewhat of a problem	21.5	28.5	16.2	23.5	19.0
A small problem	28.3	26.4	30.1	37.0	22.5
No problem	42.0	35.9	44.1	35.8	52.8

NOTE: CPD is continuous peritoneal dialysis.

Table 5-34

Percent distribution of patients with end stage renal disease, by treatment modality and their feelings concerning their dependence on others

	Treatment modality				
Nature of dependence	All modalities	Home hemodialysis	In-center hemodialysis	CPD	Transplant
			Percent distribution		
Total	100.0	100.0	100.0	100.0	100.0
Are more dependent on others than would like to be	49.0	59.6	45.8	58.7	30.6
Would like to have someone to depend on more	6.7	4.6	9.9	2.5	5.6
Neither	44.3	35.8	44.3	38.7	63.9

NOTE: CPD is continuous peritoneal dialysis.

Table 5-35

Percent distribution of patients with end stage renal disease, by treatment modality and their perceived health status as compared with others of the same age

How does health status compare with others?	Treatment modality				
	All modalities	Home hemodialysis	In-center hemodialysis	CPD	Transplant
	Percent distribution				
Total	100.0	100.0	100.0	100.0	100.0
Better	12.3	8.9	15.3	12.5	11.9
About the same	34.9	31.0	35.1	26.2	46.9
Poorer	52.8	60.1	49.5	61.2	41.3

NOTE: CPD is continuous peritoneal dialysis.

Table 5-36

Percent distribution of patients with end stage renal disease, by treatment modality and level of satisfaction with their current health

Level of satisfaction	Treatment modality				
	All modalities	Home hemodialysis	In-center hemodialysis	CPD	Transplant
	Percent distribution				
Total	100.0	100.0	100.0	100.0	100.0
Very satisfied	18.1	16.4	12.5	14.8	36.8
Satisfied	44.2	40.9	46.7	43.2	45.1
Neither satisfied nor dissatisfied	16.6	19.2	15.9	19.8	11.1
Dissatisfied	15.9	18.5	18.8	14.8	4.2
Very dissatisfied	5.3	4.9	6.1	7.4	2.8

NOTE: CPD is continuous peritoneal dialysis.

Table 5-37

Percent distribution of patients with end stage renal disease, by treatment modality and their perceived health status

Health status	Treatment modality				
	All modalities	Home hemodialysis	In-center hemodialysis	CPD	Transplant
	Percent distribution				
Total	100.0	100.0	100.0	100.0	100.0
Excellent	11.6	7.7	9.0	4.9	29.4
Good	39.5	46.8	31.9	39.5	43.4
Fair	36.9	33.8	45.8	35.8	22.4
Poor	12.0	11.6	13.3	19.8	4.9

NOTE: CPD is continuous peritoneal dialysis.

Dependence is viewed as somewhat of a problem and a small problem by 21.5 percent and 28.3 percent of patients, respectively. However, most patients (42.0 percent) felt that their dependence on others has been no problem. This feeling is also reflected in Table 5-34. Overall, 49.0 percent of ESRD patients felt that they are more dependent on others than they would like to be, and only 6.7 percent would like to have someone to depend on more.

Perceived health status

Perceived health status is considered to be an important aspect of patient's recovery from severe illness and their ability to cope with chronic disease. Patients with end stage renal disease (ESRD) are not cured of their disease. Dialysis patients must watch their diet and fluid intake, take drugs prescribed by their doctor, and dialyze on a regular basis. Even transplant patients must continue to take immunosuppressive drugs that have a variety of untoward side effects. These drugs, necessary to combat rejection, may ultimately threaten the transplant patient's health and well-being.

Patients were first asked how their health compared with the health of other people their age. As shown in Table 5-35, 12.3 percent of all patients considered their health to be better, 34.9 percent felt their health was about the same, and 52.8 percent regarded their health to be poorer than other people their age. Patients were then asked how satsfied they were with their health at the present time. Overall, ESRD patients were quite satisfied with their health (Table 5-36). Across all modalities 18.1 percent said that they were very satisfied, and 44.2 percent indicated that they were satisfied with their health. Only 21.2 percent of patients were either dissatisfied or very dissatisfied with their current health. Not surprisingly, transplant patients were most satisfied with their health.

Patients were then asked to rate their current health status and to compare their current health with their health 5 years ago. When asked to rate their overall health at the present time, 11.6 percent of all patients rated their health as excellent; 39.5 percent, as good; 36.9 percent, as fair; and 12.0 percent, as poor. However, as shown in Table 5-37, transplant patients rated their current health status much higher than the other three modality groups. When asked to compare their current health status with their health status 5 years ago, 30.3 percent of all patients said that their current health status is better, 22.7 said that it was about the same, and 47.1 percent said that it was worse than 5 years ago (Table 5-38). Again, the responses of the transplant group differ considerably from the other three treatment modalities. Most transplant patients (53.8 percent) felt that their current health status is better than 5 years ago, and only 18.2 percent felt that it is worse.

Employment

The current employment status of the patients with end stage renal disease (ESRD) included in the study and their employment status 1 year prior to their first maintenance dialysis are presented in Table 5-39. One year before dialysis, 67.1 percent of all ESRD patients were employed either full time or part time; however, only 29.7 percent were working either full time or part time at the time of the survey. Currently, 39.2 percent are unable to work because of their health, whereas only 8.2 percent were disabled 1 year prior to dialysis. The percent currently employed full time is highest in the case of transplant patients (40.3 percent) and lowest for patients on in-center hemodialysis and those on continuous peritoneal dialysis (CPD).

Of those patients currently working or temporarily laid off, 60.9 percent were working for the same employer as before they began dialysis, and 66.4 percent were doing the same kind of work that they did before they began dialysis (another 5.2 percent were doing the same kind of work but switched to part-time work). Those patients currently unemployed, disabled, and retired were asked why they left their last job. Of these patients, 69.9 percent quit because of their health, 8.8 percent quit for some other reason, 10.8 percent retired, 4.6 percent were laid off, 1.8 percent were fired, and 4.2 percent gave some other reason. Patients were then asked if they had to stop working because of either a time problem or a physical limitation associated with their kidney disease. A time problem was cited by 17.8 percent of the patients, and physical limitation was indicated by 58.7 percent. However, 37.3 percent of all patients said neither a time problem nor physical limitation was a factor.

Those patients currently employed were asked if their employer did anything special for them because of their health problem to make it easier for them to work at their job. Similarly, those patients currently unemployed, disabled, and retired were asked if their last employer did anything to make work easier. Among those currently employed, 49.2 percent indicated that their employers had done something to make work easier. Among those currently not working, 24.8 percent indicated that their last employer had done something to help (10.7 percent said they had no health problem at the time). Those patients that said their employers had done something to help were asked what their employers had done. As can be seen in Table 5-40, the responses most commonly given include made work a little easier or changed job to something they could do; shortened their workday; changed the time they came to and left work; and allowed more breaks and rest periods.

Table 5-38

Percent distribution of patients with end stage renal disease, by treatment modality and perceived health status now as compared with 5 years ago

	Treatment modality				
Health status	All modalities	Home hemodialysis	In-center hemodialysis	CPD	Transplant
	Percent distribution				
Total	100.0	100.0	100.0	100.0	100.0
Better	30.3	28.3	22.0	30.9	53.8
About the same	22.7	24.5	22.5	7.4	28.0
Worse	47.1	47.2	55.5	61.7	18.2

NOTE: CPD is continuous peritoneal dialysis.

Table 5-39

Prior and current employment status, by modality

Treatment modality	Total	Employed full time	Employed part time	Employed but temporarily laid off	Unemployed but looking for work	Unemployed not looking for work	Unable to work of health (disabled)	Homemaker	Student Full time	Retired
1 year before dialysis					Percent distribution					
All modalities	100.0	60.3	6.8	0.2	0.2	1.0	8.2	11.0	7.3	5.0
Home hemodialysis	100.0	64.1	5.9	0.0	0.0	0.3	8.4	11.1	7.3	2.8
In-center hemodialysis	100.0	58.4	8.7	0.3	0.6	1.7	8.7	11.3	2.9	7.5
Continuous peritoneal dialysis	100.0	55.6	4.9	1.2	0.0	1.2	14.8	9.9	2.5	9.9
Transplant	100.0	59.7	4.9	0.0	0.0	0.7	2.8	10.4	20.8	0.7
Current employment status										
All modalities	100.0	22.3	7.4	0.6	3.2	2.9	39.2	11.3	2.5	10.7
Home homeodialysis	100.0	26.8	9.4	1.0	2.4	1.0	35.9	12.2	3.5	7.7
In-center hemodialysis	100.0	13.0	7.5	0.3	2.9	3.2	46.2	9.8	0.9	16.2
Continuous peritoneal dialysis	100.0	13.7	2.5	0.0	0.0	7.5	47.5	11.2	1.2	16.2
Transplant	100.0	40.3	5.6	0.7	6.9	3.5	24.3	13.2	4.9	0.7

Table 5-40

Number of patients with end stage renal disease who are currently employed and number who are currently unemployed, disabled, or retired, by what their employers did to help make it easier for them to work

What employer did	Number of currently employed patients	Number of currently unemployed, disabled or retired patients
Got someone to help me	13	19
Made work a little easier or changed job (tasks) to something I could do	37	58
Helped me learn new skills	2	3
Shortened my work day	31	38
Changed time I came to and left work	39	19
Allowed me more breaks and rest periods	19	31
Got me special equipment for the job	2	3
Arranged special transportation	1	2
Other	27	29

Conclusion

Based on the foregoing, it is apparent that end stage renal disease patients are a diverse group of chronically ill people. Not surprisingly, many differences among patients are clearly associated with their treatment modality. Patients on some modalities have various problems that other patients do not have. It is quite possible that some of these differences reflect the case mix of patients on each of the treatment modalities. It is equally likely, however, that certain treatment modalities afford patients certain experiences that others do not. For example, transplant patients may be more independent because they are not dependent upon a mechanical life-saving therapy such as dialysis. It is along these same lines that hemodialysis represents an imposition upon family routine. In-center patients have to visit a dialysis center regularly, and home patients must set aside both space and time to permit dialysis. Transplant recipients are free from such constraints.

Throughout this discussion of patient differences according to treatment modality it is relatively easy to offer explanations that lend plausability to the results. In-center patients are generally older, and they have a variety of complications that preclude treatment by other means. A large proportion of home hemodialysis patients are male because of the need for a home dialysis assistant—female spouses are more likely than male spouses to assist with dialysis. Not surprisingly, black persons make up a smaller proportion of the patients on home hemodialysis, continuous peritoneal dialysis, and transplantation than they do on in-center hemodialysis. All patient groups seem reasonably well-educated although it is not surprising that in-center patients have a lower level of education. Being on the whole the younger of all patients, transplant recipients have a greater probability of being single (never married). Home hemodialysis patients are the most likely to be married, and a much higher percent of in-center hemodialysis patients are widowed or divorced.

Primary disease diagnosis is among the more interesting of the medical characteristics. Of the various treatment modalities, the largest percent of diabetics is on continuous peritoneal dialysis (CPD), and the smallest percent has had transplants. Once again, this is to be expected as CPD is appropriate for patients who have exhausted blood access sites, as diabetics frequently do. Also, diabetics are often considered to be among the less desirable candidates for transplantation.

A greater prevalence of comorbidity was found among in-center hemodialysis patients, and transplant patients had the least comorbidity. The problems present among transplant recipients are probably largely a result of immunosuppressive therapy; but even in cases where conditions such as bone disorders known to be related to immunosuppression, dialysis patients have a greater prevalence than transplant recipients.

The foregoing factors, including length of time on current treatment modality and experience with a failed transplant, are all considered important case-mix factors that may account for differences in patient outcomes. When examining outcomes such as quality of life, disability, health status, and work status, these factors as much as treatment modality may be significant determinants. Even one's social relationships and personal adjustment can be markedly affected by both treatment modality and case-mix variables. Throughout the remainder of this report, this general theme will be emphasized. The National Kidney Dialysis and Kidney Transplantation Study was concerned as much with case-mix differences as it was with treatment modality. Moreover, although analyses of the cost of treatment frequently emphasize differences across modalities, it is also true that patient case mix can be a key determinant in the cost of treatment—sicker patients are more expensive to care for than healthier patients. Thus, a second general theme concerns the relationship among treatment modality, patient outcomes, and costs. It is apparent that each of these is simultaneously related to the others. Subsequent chapters will elaborate further upon these two basic underlying themes.

References

Campbell, A., Converse, P.E., and Rodgers, W.L.: The Quality of American Life. New York. Russell Sage Foundation, 1976.

Quality of life

Chapter 6. Comparative assessment of life quality

Introduction

The cost of the Medicare end stage renal disease (ESRD) program continues to increase, and expenditures for 1985 are expected to be $2.3 billion (Kunkel, 1984). Although the annual cost per patient has decreased (when adjusted for inflation) (Rettig, 1980a; 1980b), rising program costs have led to questions about the future of the ESRD program that include expressions of concern about whether all patients truly benefit from long-term dialysis and kidney transplantation. Several studies have suggested that benefits derived by some ESRD patients are limited (Gutman et al., 1981; Rennie, 1981; Tews et al., 1980; Poznanski et al., 1978). Thus, even though the ESRD program has saved the lives of many patients, attention is being focused on the quality of their lives (Editorial, 1981; Caplan, 1981).

Gutman and associates (1981) suggested that dialysis patients were doing poorly with respect to objective indicators of life quality such as employment status and physical activity. Only 60 percent of nondiabetic and 23 percent of diabetic patients were said to be capable of physical activity beyond caring for themselves, and only 25 percent of patients were working outside their homes. No attempt was made to relate outcome to treatment modality. They concluded that "...there is a need for improved data on the quality and length of life of patients on maintenance dialysis."

Subsequently, Johnson and associates (1982) reported that objective and subjective indicators of life quality were weakly correlated and that hemodialysis patients and patients with a successful cadaver transplant resembled the general population in terms of subjective quality of life (i.e., well-being, life satisfaction, psychological affect). On the other hand, failed transplant patients showed a quality of life that was somewhat lower than that of other ESRD patients and substantially lower than that of the general population. Objectively, there was greater physical and occupational rehabilitation among patients with successful transplants than among those on hemodialysis.

With one exception (Evans, 1979a; 1979b), all studies of ESRD patients that have related outcomes to treatment modalities exhibit serious flaws, the most important of which is failure to take into consideration patient case mix (Gutman et al., 1978; 1981; Tews et al., 1980; Poznanski et al., 1978; Johnson et al., 1982; Atcherson, 1978; Beard, 1971; Bergsten et al., 1977; Blagg, 1978; Blagg et al., 1973; Freeman, 1979; Ginn et al., 1979; Guttmann, 1979; Hughson et al., 1974; Jackle, 1974; Kaplan DeNour et al., 1980; Kutner et al., 1981; Levy et al., 1975; Naish, 1979; Richmond et al., 1982; Simmons et al., 1977; Sophie et al., 1979; Editorial, 1980). Furthermore, there has been no study in which subjective and objective indicators of life quality among patients on the four major treatment modalities—home hemodialysis, in-center hemodialysis, continuous peritoneal dialysis (CPD), and transplantation—have been compared. Only Johnson and coworkers (1982) have specifically examined quality of life of patients after a failed transplant.

In this chapter, results from the National Kidney Dialysis and Kidney Transplantation Study concerning patient case mix and its relationship to quality of life are reported. Patient case-mix variables are related to objective (i.e., ability to work and functional impairment) and subjective (i.e., psychological affect, well-being, life satisfaction) indicators of life quality. By controlling for case mix, comparisons of quality of life across treatment modalities become more meaningful.

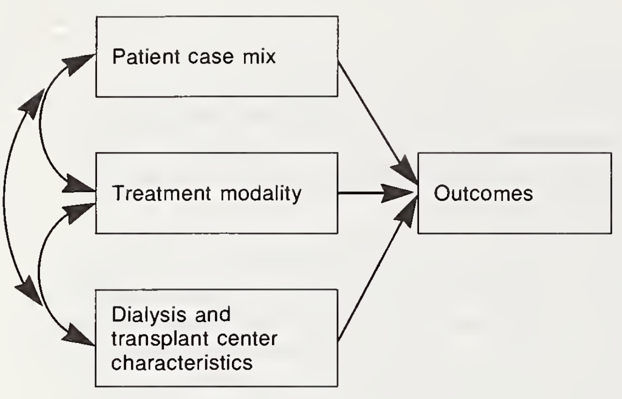
Methods

Conceptual model

The case mix of patients treated by home hemodialysis, in-center hemodialysis, continuous peritoneal dialysis (CPD), and transplantation is different in terms of both medical and sociodemographic characteristics. For example, in-center hemodialysis patients are generally older and sicker than those on home hemodialysis (Evans, 1979a; 1979b), and transplant recipients are more likely to be younger and healthier than patients on any form of dialysis. An association between outcomes of patients with end stage renal disease (ESRD) and treatment modality (Gutman et al., 1978; Whalen et al., 1978; Jenkins, 1977) has been shown in many studies, but it has not yet been shown that case-mix differences rather than treatment modality are the major determinant of outcomes—younger and healthier patients, regardless of treatment modality (Evans, 1979a; 1979b; Gutman et al., 1978), may have better outcomes than older, sicker patients. In other studies, an association between patient characteristics and outcomes has been acknowledged, but no consideration has been given to the fact that outcome differences are at least partially attributable to dialysis and transplant center differences—patients treated at centers emphasizing rehabilitation are likely to be better rehabilitated (Evans, 1979a; 1979b). Thus, it is important to consider the potential impact of the following factors, each of which can uniquely affect outcomes: patient case mix, treatment modality, and dialysis and transplant center characteristics (Figure 6-1). Although a single category of variables may produce differences, outcomes are more likely to be influenced by several factors, and these may combine to produce interaction effects whereby two or more variables produce a unique or synergistic effect (Cohen et al., 1975). Factors that influence patient outcomes also may be correlated with each other (Figure 6-1).

Case-mix differences are of two types—intermodality and intramodality. Intermodality case-mix differences are

Figure 6-1
Factors influencing patient outcomes



NOTE: Straight arrows indicate possible causal effects, and the curved arrows indicate correlations.

those observed between treatment modalities—patients on home and in-center hemodialysis and those on CPD and transplantation may be quite different in terms of factors such as age, sex, comorbidity. However, examination of only intermodality differences ignores case-mix differences peculiar to individual centers. Intramodality case-mix differences, not described in detail here, are those observed within a treatment modality across dialysis and transplant centers. For example, the case mix of home hemodialysis patients at one center may be quite different from that at another center, or the patient case mix of a center that transplants diabetics will be quite different from that of one that does not. Thus, intramodality case-mix differences describe treatment modalities and centers in terms of the homogeneity or heterogeneity of their patients.

Patient groups

The analyses undertaken here focus on four different treatment modalities: in-center hemodialysis, home hemodialysis, CPD, and transplantation. Patients were grouped based on treatment modality at the time of study. All patients in the transplant group had functioning grafts (time since last transplant was 1-194 months, median = 42 months).

Variables

The following four major categories of variables were analyzed: sociodemographic, medical, objective indicators of life quality, and subjective indicators of life quality. Sociodemographic variables—age, sex, race, and education—were included to control for patient case-mix differences (Chapter 5). In addition to treatment modality, two medical variables (comorbidity and whether a dialysis patient previously had a failed transplant) were used.

An index of comorbidity to measure current health status was constructed (Chapter 5) based on the presence of the following:

- Angina, myocardial infarction.
- Other cardiovascular problems.
- Respiratory disease.
- Gastrointestinal problems.
- Neurological problems, cerebrovascular accident, stroke.
- Musculoskeletal disorders, including bone disease.
- Infection other than access site infection and peritonitis.
- Hepatitis.
- Hematologic problems other than anemia.
- Spinal abnormalities (lower back problems, arthritis).

The index of comorbidity was defined as the total number of these 10 specific conditions reported for that patient.

A previously failed transplant may be an important determinant of quality of life among dialysis patients (Johnson et al., 1982) and, consequently, "failed transplant" was included as an independent case-mix variable.

Two variables, functional impairment and ability to work at a job for pay, serve as objective indicators of life quality. The Karnofsky Index was used as an indicator of functional impairment, and it is a measure of overall physical functional status ranging from 1 (normal; no complaints; no evidence of disease) to 10 (moribund; fatal processes progressing rapidly). Ability to work was determined by the patient's answer to the question: "Are you now able to work for pay full-time, part-time, or not at all?"

Both functional impairment and ability to work are considered objective indicators of life quality because they reflect physical status. Subjective indicators reflect socioemotional status, well-being, life satisfaction, and psychological affect. Even though each patient's level of functional impairment was assessed by staff, ability to work, life satisfaction, well-being, and general affect are all self-perceived. (Self-perceived ability to work, although not a true objective indicator, is much more objective than self-perceived socioemotional status.)

The subjective indicators of life quality were taken from the survey, The Quality of American Life, 1978, conducted by the Institute for Social Research at the University of Michigan (Campbell et al., 1976; Campbell and Converse, 1980). Indicators used in the present study include the Index of Psychological Affect, the Index of Overall Life Satisfaction, and the Index of Well-Being. The Index of Psychological Affect, based on eight bipolar items, describes how patients feel about their present life, and responses are averaged for a mean score. The Index of Overall Life Satisfaction is also based on bipolar responses. The Index of Well-Being is calculated by combining the Index of Overall Life Satisfaction and the Index of Psychological Affect (giving slightly more weight to the former).

Both the Index of Psychological Affect and the Index of Overall Life Satisfaction range from a low of 1.0 (completely dissatisfied) to a high of 7.0 (completely satisfied). The Index of Well-Being ranges between 2.1 and 14.7, where a score of 2.1 indicates low well-being and a score of 14.7 indicates high well-being.

Statistical methods

Several statistical techniques were used to test the significance of differences in quality of life, patient characteristics, and other relevant variables across modality groups. One-way analysis of variance was used to test the difference of means of variables (e.g., age, education, subjective indicators of life quality) across patient groups (Glass et al., 1970). Differences in distribution of patients across treatment modalities according to variables such as race and primary diagnosis were determined, using the chi-square test (Armitage, 1971; Brown and Hollander, 1972; Box et al., 1978). Simple bivariate correlation analysis was used to test the degree of correlation between indicators of objective and subjective quality of life (Glass et al., 1970). Multiple-classification analysis, a variant of dummy variable multiple regression and a type of covariance analysis, was used to determine whether modality differences persisted in the various outcome variables once initial patient case-mix differences were statistically held constant (Sonquist, 1970; Andrews et al., 1973; Nie et al., 1975). Finally, the t-test was used to test for quality of life differences between treatment groups and the general population.

Results

The primary objective of these analyses is to examine the objective and subjective quality of life of patients with end stage renal disease on four different treatment modalities. Because many of the factors that affect the patient's choice of or assignment to treatment modality (i.e., age, sex, race, education, health status) also affect quality of life, the fundamental question is to what extent a relationship exists between treatment modality and quality of life, controlling for patient case mix (i.e., sociodemographic and medical characteristics).

Descriptive case-mix analyses

Sociodemographic characteristics

Sociodemographic characteristics of the patients by treatment modality and overall are summarized in Table 6-1. As noted in Chapter 5, transplant patients are younger than the patients in all other modality groups (mean age 37.2 years), and in-center hemodialysis patients are older (mean age 51.9 years). One-way analysis of variance indicates that the differences in mean ages of the groups are statistically significant ($F = 39.3$, $p = .0000$).

Distribution of patients across treatment modalities by sex is also significantly different (chi-square = 16.2, $p = .0001$). A larger proportion of males are on home hemodialysis and transplantation, males and females are evenly divided for in-center hemodialysis, and a slightly higher percent of females are on continuous peritoneal dialysis (CPD).

There are also significant differences in the racial composition of the patient groups (chi-square = 123.1, $p = .0000$). Home hemodialysis patients, CPD patients, and transplant patients are predominantly white, and black patients are represented in disproportionately high numbers among in-center hemodialysis patients.

The average educational level for all patients is 12.1 years, and differences across treatment modalities, although small, are significant when one-way analysis of variance is used ($F = 9.3$, $p = .0000$). Home hemodialysis patients are better educated than other groups, being markedly different from patients on in-center hemodialysis and CPD although the difference is less between home hemodialysis and transplant patients.

Sociodemographic factors may be critical to patient outcomes. For example, approximately 75 percent of CPD and home hemodialysis patients were married, and about 80 percent owned their own home. Patients with

Table 6-1

Mean age and years of education of patients with end stage renal disease by treatment modality and percent distribution, by age, race, and treatment modality

	Treatment modality				
Characteristic	All modalities	Home hemodialysis	In-center hemodialysis	CPD	Transplant
			Mean		
Age	47.6	47.0	51.9	49.8	37.2
			Percent distribution		
Sex:					
Male	55.4	64.1	50.0	45.7	56.3
Female	44.6	35.9	50.0	54.3	43.8
Race:					
Black	23.0	8.7	42.5	9.9	11.8
White	72.6	86.4	53.5	84.0	84.7
Other	4.4	4.9	4.0	6.2	3.5
			Mean years		
Education	12.1	12.8	11.5	11.9	12.2

NOTE: CPD is continuous peritoneal dialysis.

successful transplants were younger, about two-thirds were married, and a similar fraction owned their own home. Both marriage and home ownership were less common among in-center hemodialysis patients.

Medical characteristics

There are significant differences in medical characteristics of patients by treatment modality. Differences in primary diagnosis, presence of comorbid conditions, months on current treatment modality, and prevalence of a failed transplant by the four treatment modalities are summarized in Table 6-2.

There are significant differences in primary diagnosis by treatment modality (chi-square value = 81.96, p = .0000) but, given variation in diagnosis of renal disease by physicians, interpretation of these differences is difficult. There are also differences across modality groups for length of time on current treatment modality (F = 24.1, p = .0000) and the percent of patients who had experienced a failed transplant. As to comorbidity, in-center hemodialysis patients reported significantly more comorbid conditions than those on other treatment modalities (F = 24.5, p = .0000); transplant patients were the least sick, having fewer comorbid conditions than any other group; and home hemodialysis and CPD patients were similar regarding comorbidity.

Correlations among indicators

A separate correlation analysis was undertaken of the intercorrelation among objective and subjective indicators of life quality. As shown in Table 6-3, the objective indicators had an intercorrelation of .42, significant at the .001 level, and subjective measures were more highly intercorrelated. (See correlation coefficients in the triangle.) This is to be expected because the Index of Well-Being is a composite index derived from the Index of Overall Life Satisfaction and the Index of Psychological Affect. Nonetheless, the separately derived Index of Overall Life Satisfaction and the Index of Psychological Affect are also highly correlated (r = .60).

Table 6-2

Percent distribution of patients with end stage renal disease, by treatment modality and medical characteristic

	Treatment modality				
Medical characteristic	All modalities	Home hemodialysis	In-center hemodialysis	CPD	Transplant
	Percent distribution				
Primary diagnosis					
Interstitial disease	10.6	11.8	7.1	15.0	14.3
Polycystic disease	10.0	15.0	8.0	10.0	5.0
Primary renal disease involving glomerular arteriolar structures	41.1	45.0	35.9	30.0	52.1
Primary hypertensive renal disease	11.1	5.0	18.7	8.8	6.4
Nephrosclerosis	6.1	2.9	9.5	6.3	4.3
Systemic lupus erythematosis	1.6	1.8	1.2	2.5	1.4
Diabetes	9.7	8.2	10.1	16.2	7.9
Myeloma	0.4	0.0	0.9	0.0	0.0
Other	9.4	10.4	8.6	11.2	8.6
Comorbidity[1]					
Angina, myocardial infarction	15.3	12.7	21.4	18.5	3.6
Other cardiovascular problem	23.2	23.6	31.7	18.5	4.3
Respiratory disease	8.5	4.6	14.4	8.6	2.2
Gastrointestinal problems	14.4	10.9	22.0	13.6	3.6
Neurological problems, cerebrovascular accident, including stroke	9.2	9.5	12.6	8.6	0.7
Musculoskeletal disorders, including bone disease	23.7	22.5	29.6	24.7	10.8
Infection other than access problems or peritonitis	3.4	2.8	4.7	2.5	2.2
Hepatitis	3.6	3.2	4.7	0.0	3.6
Hematologic problems other than anemia	2.7	2.5	4.1	1.2	0.7
Spinal abnormality, lower back problem, arthritis	6.4	5.3	10.3	3.7	0.7
Mean number of comorbid conditions	1.10	0.98	1.55	1.00	0.32
Mean months on current modality	41.0	46.6	38.9	11.4	51.3
Percent of failed transplant	12.5	18.1	12.7	13.6	0.0

[1] Totals may be greater than 100.0 percent because patients may have more than one condition.

Table 6-3

Pearson correlation coefficients among objective and subjective indicators of quality of life of patients with end stage renal disease

Indicator	Functional impairment	Ability to work	Well-being	Psychological affect
Functional impairment[1]				
Ability to work[2]	.42			
Well-being[3]	.16	.22		
Psychological affect[4]	.18	.24	.85	
Life satisfaction[5]	.12	.16	.93	.60

[1] Scored as 1 = poor, through 10 = good.
[2] Scored as 0 = unable to work, through 100 = able to work.
[3] Scored as 2.1 = low well-being, through 14.7 = high well-being.
[4] Scored as 1.0 = negative affect, through 7.0 = positive affect.
[5] Scored as 1.0 = dissatisfied, through 7.0 = satisfied.

NOTE: All significant at .001 level.

The intercorrelations between subjective and objective quality of life indicators are shown in Table 6-3. (See correlation coefficients in the rectangle.) Although these intercorrelations are all significant at the .001 level, they are not as highly intercorrelated with each other as the objective measures separately and the subjective measures separately. Thus, even though objective and subjective indicators are related, they constitute separate dimensions or aspects of quality of life as measured in this study, and it is conceivable that there may be other dimensions. The quality of life variables are all positively correlated indicating, for example, that patients able to work have a higher quality of life than those who cannot, and that patients with minimal functional impairment have a better quality of life than those physically impaired.

Independent analyses of life quality

Objective indicators

Presented in Tables 6-4 and 6-5 are analyses of functional impairment and ability of patients to work according to treatment modality. Differences were first examined across modality groups, and then multiple classification analysis was used to examine differences after statistically adjusting for case mix (e.g., sociodemographic and medical characteristics). Both unadjusted and adjusted mean scores are shown in Table 6-4.

The raw or unadjusted scores indicate that transplant patients experience less functional impairment than patients in the other three modality groups, and in-center hemodialysis patients are most limited in physical activities. These differences across modalities are significant at the .0000 level. Overall, patients scored an average of 2.73 on the indicator of functional impairment.

With respect to ability to work, 49.6 percent of all patients indicated that they were currently able to work for pay either full time or part time. Significant differences were observed for patients on the various treatment modalities—74.1 percent of transplant patients but only 24.7 percent of the CPD patients said they were able to work. A much higher percent of home hemodialysis patients (59.3 percent) than of in-center hemodialysis patients (37.2 percent) was able to work, using unadjusted scores.

Comparing the case-mix adjusted mean scores reveals that there is less variation in the two objective indicators of life quality across the four modality groups, but the in-center hemodialysis group is replaced by the CPD group as the patient group with the greatest functional impairment. As shown in Table 6-4, however, on the ability to work variable, the overall outcome did not change after case mix was controlled. Transplant patients remained the most able to work and CPD patients the least able.

Various case-mix factors were found to be related to both objective quality of life indicators. As shown in Table 6-5, age, education, and comorbidity had a significant effect on functional impairment and ability to work. Although sex had a significant effect on ability to work (males were more often able), race, previously failed transplant, and length of time on current treatment modality were not significant determinants of functional impairment nor of ability to work.

Subjective indicators

Analyses of three subjective indicators of life quality—well-being, psychological affect, and life satisfaction—are also shown in Tables 6-4 and 6-5. As with the objective measures, differences in these indicators were first examined across the patient groups, and then multiple classification analysis (MCA) was used to examine differences in these indicators after adjusting for the influence of case mix.

Presented in Table 6-4 are unadjusted and MCA-adjusted mean scores for the subjective indicators of life quality. As with the objective measures, significant differences in all three subjective indicators were observed across the four treatment modalities. Comparing unadjusted mean scores for all three indexes, transplant patients seemed the most satisfied with the quality of their lives, and in-center hemodialysis patients, the least.

The case-mix adjusted mean scores (Table 6-4) also show that transplant patients appear most and in-center hemodialysis patients least satisfied with their life quality. In addition to treatment modality, patient age, education, and race are important factors underlying the observed variation in subjective indicators of life quality (Table 6-5). As with objective quality of life, length of time on current modality showed no significant relationship to subjective quality of life, but comorbidity, an important determinant of objective quality of life, was not significant in the case of subjective quality of life. Similarly, sex and a previously failed transplant were not significant determinants of subjective quality of life. More detailed analyses of the relationship of marital status and home ownership revealed that, although these variables were significant determinants of quality of life

Table 6-4

Objective and subjective indicators quality of life unadjusted for case mix and case-mix adjusted percents and mean scores, by treatment modality

Indicator of life quality	All modalities	Home hemodialysis	In-center hemodialysis	CPD	Transplant	*p*-value	Home hemodialysis	In-center hemodialysis	CPD	Transplant	*p*-value
	Unadjusted						Adjusted				
Objective											
Functional impairment (mean)	2.73	2.56	3.11	3.01	1.96	.0000	2.63	2.85	3.00	2.37	.001
Ability to work (percent)	49.6	59.3	37.2	24.7	74.1	.0000	54.8	44.8	27.8	62.3	.001
Subjective											
Well-being (mean)	11.09	11.12	10.77	11.05	11.83	.0012	11.23	10.56	11.08	12.18	.001
Psychological affect (mean)	5.33	5.42	5.15	5.24	5.62	.0010	5.47	5.09	5.26	5.72	.001
Life satisfaction (mean)	5.25	5.19	5.11	5.30	5.66	.0060	5.25	4.99	5.30	5.90	.001

NOTE: CPD is continuous peritoneal dialysis.

Table 6-5

Significance of variables included in the multiple classification analyses

	Variables (independent and covariates)[1]							
Dependent variables	Modality	Sex	Race	Age	Education	Comorbidity	Failed transplant	Length of time on current treatment modality
Objective indicators of life quality								
Functional impairment	X	NS	NS	X	X	X	NS	NS
Ability to work	X	X	NS	X	X	X	NS	NS
Subjective indicators of life quality								
Well-being	X	NS	X	X	X	NS	NS	NS
Psychological affect	X	NS	X	X	X	NS	NS	NS
Life satisfaction	X	NS	X	X	X	NS	NS	NS

[1] All variables, both independent and covariates, have been entered in the analyses simultaneously.

NOTES: Significant if *F*-test in analysis of variance table is less than or equal to .05. X = the effect of the variable was statistically significant. NS = not significant.

when combined with the other case-mix factors, they did not eliminate the unique effect of treatment modality.

Pairwise comparisons of modality differences

These analyses show that significant differences exist among the four groups in terms of both objective and subjective measures of quality of life. These differences persist even after controlling for case mix, suggesting that a unique treatment modality effect exists. However, analyses of variance tests do not indicate which pairs of modality means are significantly different from each other (Glass and Stanley, 1970); they only show that the mean scores between at least two modalities are sufficiently different to make the overall analysis of the variance test statistic significant.

To gain a better understanding of the observed modality differences, pairwise multiple-classification analyses were done on all five measures of life quality, controlling again for patient case mix. In addition, the same multiple classification analyses were done on dialysis patients only (i.e., home hemodialysis, in-center hemodialysis, and CPD patients). Results of these comparisons are seen in Table 6-6, which shows which pairwise modality differences are significant at the .05 level for the particular indicator.

Table 6-6

Analysis of variance comparisons of objective and subjective indicators of quality of life, by significance of treatment modality

	Objective indicators of life quality		Subjective indicators of life quality		
Patient group	Functional impairment	Ability to work	Well-being	Psychological affect	Life satisfaction
All patient groups	Yes	Yes	Yes	Yes	Yes
Dialysis patient groups only (i.e., home, and in-center hemodialysis, CPD)	Yes	Yes	Yes	Yes	No
Pairwise comparisons[1]					
Home with in-center	No	Yes	Yes	Yes	No
Home with CPD	Yes	Yes	No	No	No
In-center with CPD	No	Yes	No	No	No
Transplant with home	Yes	No	Yes	No	Yes
Transplant with in-center	Yes	Yes	Yes	Yes	Yes
Transplant with CPD	Yes	Yes	Yes	Yes	Yes

[1] If a statistically significant difference was found, the first group listed had a higher quality of life than the group it was paired with.

NOTE: CPD is continuous peritoneal dialysis.

With respect to functional impairment, in-center hemodialysis patients were not significantly different from home hemodialysis or CPD patients. All other pairwise differences were significant. In terms of ability to work, all pairwise comparisons were significant with the exception of home hemodialysis and transplant patients.

The subjective indicators of quality of life reveal a more complex pattern of relationships. Pairwise comparisons of the psychological affect indicator reveal that three of the six modality pairs were significantly different, but CPD patients did not differ from either in-center or home hemodialysis patients and home hemodialysis patients did not differ from transplant patients. Similarly, with the life satisfaction indicator, only three pairs were significantly different—transplant patients are different from each of the dialysis groups. This is confirmed by the multiple-classification analysis, excluding transplant patients—no difference in life satisfaction was seen among the three dialysis groups. Analysis of the well-being indicator yields results similar to those for the psychological affect indicator except that home hemodialysis and transplant patients differ significantly in their level of well-being.

In summary, transplant patients were found to be different from the other patient groups. After controlling for case mix, transplant and home hemodialysis patients were similar in many respects, as were in-center hemodialysis and CPD patients. Even when transplant patients were excluded from the analyses, important differences in quality of life persisted among patients on the three dialysis treatment modalities.

Comparisons with general population

Unfortunately, most studies of patients with end stage renal disease (ESRD) have failed to include comparison groups such as nondialyzed renal patients, patients with other chronic diseases, or the general population (Osberg et al., 1980; Yanagida and Streltzer, 1979). In this study, use of standard measures of variables permits comparisons with the general population for estimates of well-being, psychological effect, and life satisfaction (Campbell et al., 1976) although no such estimates are available for functional impairment measured by the Karnofsky Index and ability to work.

Although data are unavailable on the proportion of the general population able to work, comparison of actual labor force participation by study patients with that of the general population provides similar information (Garrison et al., 1983). The labor force participation rates for patient groups were 53.5 percent for transplant patients; 39.6 percent for home hemodialysis patients; 23.7 percent for in-center hemodialysis patients; and 16.2 percent for CPD patients. The rank order is the same as the ability-to-work variable. Before the onset of ESRD, 67.1 percent of the patients were labor force participants, comparing favorably with the labor force participation rate of the general population, which was 63.8 percent in 1981 (*Economic Report of the President*, 1981). Following the onset of ESRD, however, the overall labor force participation rate for patients dropped to 33.5 percent. Thus, ESRD patients appear worse off in this regard than the general population, but factors such as availability of Government disability payments may be partly responsible.

A comparison is made in Table 6-7 of ESRD patients and the general population in terms of subjective indicators of life quality. Unadjusted scale scores for ESRD patients and for the general population are not substantially different, indicating that the subjective quality of life of ESRD patients as a whole may not be as bad as has been suggested. Nevertheless, on the basis of absolute scale scores, dialysis patients, unlike transplant patients, have a lower subjective quality of life than the general population. In all instances the differences among modality-specific mean scores for

Table 6-7

Mean unadjusted quality of life indicator scores, standard deviations, t values, and significance levels for all ESRD patient modality groups compared with the general population

Quality of life indicators	Mean scale score	t value[1]	Significance level	Number of cases
Life satisfaction				
Transplant patients	5.66	.94	NS	143
Home hemodialysis patients	5.19	3.71	.001	286
In-center hemodialysis patients	5.11	4.58	.001	342
CPD patients	5.30	1.32	NS	81
All ESRD patients	5.25	4.82	.001	852
General population	5.55	—	—	2,134
Psychological affect				
Transplant patients	5.62	.55	NS	143
Home hemodialysis patients	5.42	2.81	.001	281
In-center hemodialysis patients	5.15	6.92	.001	337
CPD patients	5.24	3.03	.001	78
All ESRD patients	5.33	6.95	.001	839
General population	5.68	—	—	2,147
Well-being				
Transplant patients	11.83	.30	NS	144
Home hemodialysis patients	11.12	3.93	.001	287
In-center hemodialysis patients	10.77	6.48	.001	345
CPD patients	11.05	2.25	.05	81
All ESRD patients	11.09	6.48	.001	857
General population	11.77	—	—	2,160

[1] The t-test used for these analyses assumes the samples are independent, the variances are unique, and the samples are differing sizes. The ordinary t is replaced by the quantity:

$$t^1 = (X_1 - X_2) / \sqrt{s_1^2 / N_1 + s_2^2 / N_2}.$$

This quantity does not follow student's t distribution when $u_1 = u_2$ (Snedecor, G.W., and Cochrane, W.G., 1980).

NOTES: CPD is continuous peritoneal dialysis. ESRD is end stage renal disease.

dialysis patients and for the general population were significant for all subjective quality of life indicators. Transplant patients report better well-being, psychological affect, and life satisfaction than the general population does, although these differences are not significant, and the results must be interpreted with caution because of the possibility of a "steroid high" (Simmons et al., 1977). However, the majority of these patients have had their transplants for a long period of time, and they are more likely to be on low doses of steroids. Finally, when the unadjusted data are aggregated across all treatment modalities, ESRD patients as a whole describe a slightly lower subjective quality of life than the general population. These differences are significant but not as markedly different as might be expected.

Discussion

These results show that there are significant intermodality case-mix differences among the patients studied with end stage renal disease (ESRD). For example, transplant and in-center hemodialysis patients are very different in both medical and sociodemographic characteristics. Analysis of how these case-mix differences relate to both objective and subjective indicators of life quality reveals that a treatment modality effect persists after statistical controls have been introduced. In other words, despite case-mix differences, transplant patients appear to have a higher quality of life than any of the dialysis patient groups. The case-mix factors that have been adjusted for statistically include age, sex, race, education, comorbidity, length of time on current treatment modality, and experience with a failed kidney transplant. Unfortunately, because of the small number of centers included in the study, it is impossible to say whether unique dialysis and transplant center effects are important in determining the quality of life of ESRD patients. Preliminary analyses of these same data, however, indicate that there are intramodality case-mix differences and outcome differences by center (Evans et al., 1982). These combined differences suggest that a dialysis or transplant center can have a unique effect on patient quality of life.

Despite demonstration of a true treatment modality effect, some case-mix variables were found to have a significant effect on quality of life. In particular, age and education consistently affected all indicators, but comorbidity affected only the objective, and race affected only the subjective indicators of life quality. Experience with a failed transplant did not affect any indicator of life quality, and sex only affected ability to work. Also, analyses that focused on length of time on current treatment modality failed to demonstrate a significant relationship between this variable and quality of life. It is noteworthy, however, that more detailed analysis of dialysis patients who have experienced a failed transplant reveals them to be younger and to have slightly fewer comorbid conditions. Also it is noteworthy that a much higher proportion of black persons have experienced a failed graft than have currently functioning grafts. It is possible that such differences are indicative of a potential patient selection bias.

Based on these results, certain treatment modalities enhance patient quality of life as measured for this analysis, despite acknowledged case-mix differences. It is also possible to rank treatment modalities according to the quality of life associated with them, although differences between the various groups are not always significant. Transplant patients consistently report a higher quality of life than patients on dialysis, although home hemodialysis patients are similar in many respects. Likewise, CPD and in-center hemodialysis patients are similar, but both report being worse off than either the transplant or home hemodialysis groups.

Finally, quality of life comparisons with the general population show that the life circumstances of patients with end stage renal disease (ESRD) may not be as poor, at least subjectively, as some have believed (Abram et al., 1971; Goldstein and Reznikoff, 1971; McKegney and Lange, 1971; Penn et al., 1971). Even though ESRD patients generally do relatively poorly on traditional objective indicators of life quality such as ability to work and functional ability, they do not report doing so poorly on subjective measures; and subjective and objective life quality indicators were poorly correlated. This has also been found in studies of the general population (Campbell et al., 1976). Future analyses should focus on these interrelationships to determine if, and in what manner, ability to work and functional impairment affect patient assessment of quality of life. This question will complicate consideration of issues of resource allocation and rationing (Reich, 1979; Evans, 1983a; 1983b).

Assessment of quality of life is complex. The results of cross-sectional studies such as this underscore the need for a longitudinal study on a clearly defined patient population. Quality of life is a state rather than a trait and is subject to variability over time, which is likely to be, at least in part, the result of modality switching. Clinicians need better data to facilitate assignment of patients to treatment modalities with the goal of enhancing quality of life. At the same time, although policymakers should be concerned with the cost of the Medicare ESRD program, they must also assure that incentives are created to induce patients to select the treatment modality for which they are best suited and to assure that clinicians assign patients in a manner consistent with patient needs. Crosnier (1981) has summarized these somewhat disparate goals as follows:

> ''The physician who has to make the decision between hemodialysis and renal transplantation for each patient must consider both the need to offer this patient the longest and most comfortable survival possible and to treat the largest number of patients in the country despite logistical and economic problems.''

It is not always easy to reconcile these objectives.

Reference was made above to current concerns about the costs and benefits of the ESRD program and how questions are beginning to be raised again about who should receive treatment for chronic renal failure. Only on objective indicators, such as ability to work or functional impairment, does it appear that the quality of life of ESRD patients is low, and there has been concern that the expected and observed rates of vocational rehabilitation among these patients are very discrepant. In a period of increasingly scarce resources and shifting priorities among health, social, and defense programs (Evans, 1983a; 1983b; Hiatt, 1982; Iglehart, 1982a; 1982b; 1982c), attention is likely to be focused on objective quality of life indicators. In many respects, these reflect the value of the patient to society or the value of the contribution they make to society, that is, their ''social worth.'' The major cost of ESRD treatment is borne by Medicare, and the ESRD patient often requires other financial assistance. Patients under 65 years of age and unemployed are also likely to be eligible for and receiving benefits through the social security disability insurance benefits program (Chapter 14). The combined outlays for these two publicly financed programs are a major concern of the Federal Government.

Although many would find the quality of life of an ESRD patient to be poor and apparently unacceptable, the results presented suggest that patients generally perceive their quality of life to be equal to or only slightly poorer than that of the general population not afflicted with chronic disease (Johnson, 1982; Simmons et al., 1977). Consequently, clinicians are faced with a paradox if quality of life is to be a consideration in decisions regarding whom to treat. Based on established standards of life quality for the normal population, ESRD patients, despite their illness, appear to have adjusted reasonably well, even though they assess their quality of life to be somewhat lower than that of the general population. This raises serious questions about using quality of life considerations in any resource rationing decisions.

Although patient selection remains a serious dilemma when quality of life is being considered, there are several reasons that attempts to assess the quality of life of ESRD patients should be continued. First, quality of life is important in identifying that treatment modality likely to yield the greatest benefits for a particular patient. When a patient is suitable for more than one treatment modality, ''expected'' quality of life may serve as a determining factor in treatment decisions. Second, if one of the goals of the ESRD program is to maximize quality of life, then policymakers should share a keen interest with clinicians in such assessment activities. Clearly these results suggest that certain treatment modalities appear to enhance patient quality of life. Finally, the fact that these results are somewhat counterintuitive should not serve to deter future assessment activities. A great deal has yet to be learned about human experience with chronic disease (Abram, 1970; 1971; 1972; Reichsman and Levy, 1974), and the quality of an ESRD patient's life, like that of a person who is healthy, may decline over time. Thus, even though the immediate patient response to dialysis and transplantation may be one of elation as described by Reichsman and Levy (1974), the long-term rigors of treatment may serve to detract from this initial response. However, it may also be the case that ESRD patients revise their life expectations after their initial experience, subsequently come to expect less, and so come to feel better off than they actually are. Although a cross-sectional study design as in the present instance permits interesting although incomplete analyses, only a longitudinal study will permit complete evaluation of the long-term effects of ESRD treatments on patients' subjective assessment of the quality of their lives.

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Chapter 7.
Additional indicators of life quality

Introduction

As revealed in the previous chapter, quality of life is a complex concept that is in need of extensive analysis in order to gain a greater understanding of the life experience of chronically ill patients. The concept is particularly relevant to patients with end stage renal disease (ESRD), where quality of life is frequently an issue but, unfortunately, rarely conceptualized properly. For these reasons, it seems particularly appropriate to present a further perspective on the subjective quality of life of ESRD patients, first comparing patients on various treatment modalities with each other and then comparing all patients with the general population (Andrews and Withey, 1974; 1976; Campbell et al., 1976; Campbell, 1976; Andrews, 1974; Rodgers and Converse, 1975).

In Chapter 6 we examined the quality of life of ESRD patients as measured by two objective and three subjective indicators of quality of life. The objective indicators comprised ability to work and functional impairment, and the subjective indicators comprised psychological affect, well-being, and life satisfaction. The results of this analysis indicated that, even after statistically controlling for case-mix differences among patients on various treatment modalities, significant differences persisted in both the objective and subjective indicators of quality of life. Transplant patients, for example, consistently reported a higher quality of life than patients on dialysis, although home hemodialysis patients are similar in many respects. Likewise, patients on continuous peritoneal dialysis and in-center hemodialysis patients are similar, but both reported being worse off than either the transplant or home hemodialysis groups.

Presented here is a comparison of the quality of life of ESRD patients as measured by 10 additional quality of life indicators. All 10 are subjective measures of quality of life. They include several indexes that attempt to measure the patient's satisfaction with life in general (i.e., the General Well-Being Index, general life satisfaction), as well as several indexes that measure the patients' satisfaction with a specific area of their life (i.e., satisfaction with savings and investments, satisfaction with standard of living, satisfaction with sex life). This analysis is largely descriptive. No attempt is made to control for case-mix differences in comparing differences in quality of life across treatment modalities. However, whenever possible, the quality of life of ESRD patients is compared with the quality of life of the general population.

Methods

Attention here is given to four different treatment modalities: in-center hemodialysis, home hemodialysis, continuous peritoneal dialysis, and transplantation. Patients were grouped based on treatment modality at the time of study. All patients in the transplant group had functioning grafts.

The following 10 subjective quality of life indicators were analyzed:

- General Well-Being Index.
- Positive Affect Scale.
- Negative Affect Scale.
- Affect Balance Scale.
- General life satisfaction.
- Satisfaction with sex life.
- Satisfaction with savings and investments.
- Satisfaction with standard of living.
- Feeling about present life (hard versus easy).
- Feeling about present life (tied down versus free).

A description of each of these variables, along with appropriate references to the published literature from which the variables were derived, is given in Table 7-1.

Although the interpretation of most quality of life variables is straightforward, a few comments are in order concerning their construction for purposes of these analyses. The first quality of life indicator is the General

Table 7-1

Description of 10 additional subjective quality of life indicators

Subjective quality of life indicator	Variable name used in analysis	Range of values	Reference
General Well-Being Index	GWB	1.0-6.0	Fazio, 1977
Positive Affect Scale	PAS	0-5	Bradburn, 1969
Negative Affect Scale	NAS	0-5	Bradburn, 1969
Affect Balance Scale	ABSCALE	1-9	Bradburn, 1969
General life satisfaction	GENSAT	1.0-2.0	Campbell et al., 1976; 1980
Satisfaction with sex life	V157	1-7	Campbell et al., 1976; 1980
Satisfaction with savings and investments	V100	1-7	Campbell et al., 1976; 1980
Satisfaction with standard of living	V82	1-7	Campbell et al., 1976; 1980
Feeling about present life (hard, easy)	V107C	1-7	Campbell et al., 1976; 1980
Feeling about present life (tied down, free)	V107H	1-7	Campbell et al., 1976; 1980

Well-Being Index which has previously been used in the Health Interview Survey conducted by the National Center for Health Statistics (Fazio, 1977). This index contains 10 questions about various aspects of the patient's life. The response to the questions are summed and then averaged to obtain a mean index score.

The next three scales—the Positive Affect Scale, the Negative Affect Scale, and the Affect Balance Scale—are based on the work of Bradburn and Caplovitz (1965) who conceptualized psychological well-being as having two dimensions, namely, positive affect and negative affect. To measure affect, respondents were asked to respond to a series of questions concerning different pleasurable and unpleasurable experiences they might have had in the past few weeks (e.g., During the past few weeks, did you ever feel very lonely or remote from other people?). Positive affect denotes pleasurable experiences or feelings, and negative affect denotes unpleasurable experiences or feelings. Because the two dimensions of affect are independent of each other, knowledge of patients' standing on one dimension does not enable a prediction of their position on the other, hence, positive and negative affect (Bradburn, 1969). Also, because positive and negative affect can be related to other measures of well-being in opposite directions, it is expected that a person high on positive feelings and low on negative feelings would be "very happy," and someone who was low on positive feelings and high on negative feelings would be more likely to be "unhappy." Thus, the Affect Balance Scale is thought to be a good indicator of a person's feelings of well-being.

The Positive Affect Scale is constructed by summing patient responses to five questions concerning positive feelings or experiences. The Negative Affect Scale, on the other hand, represents the sum of five questions concerning negative feelings or experiences. The Affect Balance Scale, with a few standard adjustments, results from transforming the differences in intensity on the Positive Affect Scale and the Negative Affect Scale.

With the exception of satisfaction with sex life, all remaining quality of life variables used in this analysis were taken from the survey, The Quality of American Life, 1978, conducted by the Institute for Social Research at the University of Michigan (Campbell and Converse, 1980). These same measures were used in a previous survey conducted by the same group in 1971 (Campbell et al., 1976).

The indicator of general life satisfaction, as well as the indicators concerning satisfaction with sex life, savings and investments, and standard of living are based on bipolar responses on a scale ranging from one (very dissatisfied) to seven (very satisfied). The two indicators on feelings concerning patients' present life, "hard versus easy" and "tied down versus free," are also bipolar. For these six indicators, mean or average scores were simply computed for all patients on each treatment modality.

The analysis presented here is primarily descriptive in nature. Unadjusted mean scores for the various quality of life indicators are compared for the four treatment modalities. One-way analysis of variance is used to test the difference of means of the quality of life variables across patient groups (Glass and Stanley, 1970). Whenever possible, the quality of life of ESRD patients is compared with the quality of life of the general population.

Results

The results presented in this chapter are divided into three sections. The first section contains a brief discussion of the correlations among the 10 additional quality of life indicators; the second examines the differences in quality of life indicators across the four treatment modalities; and the third contains a comparison of the quality of life of patients with end stage renal disease with that of the general population.

Correlations among indicators

The concept of quality of life is multidimensional. Thus, no single measure can adequately reflect quality of life. Some studies have focused on objective indicators of quality of life (e.g., ability to work), and others have focused on subjective indicators (e.g., overall life satisfaction). To the extent that different variables may reflect the same dimension, the measures, of course, will be intercorrelated.

The 10 additional quality of life indicators presented in this chapter are intended to measure different aspects of quality of life. Several variables—General Well-Being Index, Positive Affect Scale, Negative Affect Scale, Affect Balance Scale, and General life satisfaction—are more general measures of life quality. Satisfaction with sex life, savings and investments, and standard of living, and feelings about present life (hard versus easy, tied down versus free) focus on much more narrowly-defined aspects of one's life experience.

Table 7-2 is a correlation matrix that contains the 10 quality of life variables included in this analysis. Not surprisingly, those variables that represent more general quality of life indicators are more highly correlated with each other than is the case with those variables that are intended to measure patients' satisfaction with a specific aspect of their life.

Differences across treatment modalities

Table 7-3 presents unadjusted mean values of the 10 additional quality of life indicators, overall and for each of the four treatment modalities. With respect to the General Well-Being Index (GWB), home hemodialysis patients ranked highest and patients on continuous peritoneal dialysis ranked lowest (Table 7-4). The difference across the four treatment modalities, however, is not statistically significant.

The next two indexes—Positive Affect Scale and Negative Affect Scale—constitute separate measures of patients' positive and negative feelings and experiences. It is interesting to note that transplant patients, who as a group ranked best in terms of positive feelings, ranked worst in terms of negative feelings. In-center hemodialysis patients ranked worst in terms of the

Table 7-2

Correlations among the 10 additional quality of life indicators

Indicator	GWB	PAS	NAS	ABSCALE	GENSAT	V157	V100	V82	V107C
PAS	.32								
NAS	−.62	−.13							
ABSCALE	.62	.74	−.75						
GENSAT	.43	.26	−.33	.40					
V157	.22	.18	−.18	.24	.21				
V100	.36	.13	−.28	.27	.27	.15			
V82	.35	.22	−.26	.31	.36	.19	.49		
V107C	.44	.17	−.28	.31	.35	.18	.34	.35	
V107H	.34	.23	−.26	.32	.29	.22	.24	.24	.38

NOTES: See Table 7-1 for a description of the indicators, but they can be identified as follows:

GWB is General Well-Being Index.
PAS is Positive Affect Scale.
NAS is Negative Affect Scale.
ABSCALE is Affect Balance Scale.
GENSAT is general life satisfaction.
V157 is satisfaction with sex life.
V100 is satisfaction with savings and investments.
V82 is satisfaction with standard of living.
V107C is feelings about present life (hard versus easy).
V107H is feelings about present life (tied down versus free).

Table 7-3

Unadjusted mean values of the 10 additional quality of life indicators, by treatment modality

Quality of life indicator	Scale values	Home hemodialysis	In-center hemodialysis	CPD	Transplant	All modalities	Significance level[1]
		Unadjusted mean scores					
General Well-Being Index (GWB)	(1.0 = Low; 6.0 = High)	4.87	4.79	4.74	4.81	4.82	.5759
Positive Affect Scale (PAS)	(0 to 5 Positive Feelings)	3.21	2.62	2.90	3.60	3.01	.0000
Negative Affect Scale (NAS)	(0 to 5 Negative Feelings)	1.70	1.82	1.86	1.93	1.80	.4812
Affect Balance Scale (ABSCALE)	(1 = Negative; 9 = Positive)	5.59	4.95	5.22	5.81	5.34	.0001
General life satisfaction (GENSAT)	(1.0 = Low; 2.0 = High)	1.69	1.67	1.67	1.73	1.69	.2436
Satisfaction with sex life (V157)	(1 = Dissatisfied; 7 = Satisfied)	4.17	4.24	3.96	5.07	4.34	.0001
Satisfaction with standard of living (V82)	(1 = Dissatisfied; 7 = Satisfied)	5.59	5.22	5.70	5.49	5.44	.0081
Satisfaction with savings and investments (V100)	(1 = Dissatisfied; 7 = Satisfied)	4.57	4.45	4.81	4.35	4.51	.4112
Feeling about present life (V107C)	(1 = Hard; 7 = Easy)	4.50	4.40	4.55	4.64	4.49	.5832
Feeling about present life (V107H)	(1 =Tied Down; 7 = Free)	4.01	4.34	4.50	5.41	4.43	.0000

[1] Based on one-way analysis of variance.

NOTE: CPD is continuous peritoneal dialysis.

Positive Affect Scale, and home hemodialysis patients ranked best with respect to the Negative Affect Scale. The difference across modalities is statistically significant in the case of the Positive Affect Scale but not in the case of the Negative Affect Scale. The Affect Balance Scale, which combines both the Positive Affect Scale and the Negative Affect Scale, reflects the same differences as were observed with respect to the Positive Affect Scale. Transplant patients ranked best, and in-center hemodialysis patients ranked worst on the Affect Balance Scale. Like the Positive Balance Scale, the difference in the Affect Balance Scale across the four treatment modalities is statistically significant.

The final general quality of life measure included in this analysis is General life satisfaction (GENSAT). Little variation is observed in this measure across the four treatment modality groups. As can be seen from Table 7-3, the difference across modalities is not statistically significant.

Unlike the preceding measures, the remaining five variables attempt to measure the patients' feelings about a more specific aspect of life. As is clearly seen in Table 7-3, a significant difference is observed across treatment modalities with respect to patients' satisfaction with their current sexual activity. Transplant patients are most satisfied, and patients on continuous peritoneal dialysis (CPD) are least satisfied with their sex life. On the other hand, little difference is observed between home hemodialysis and in-center hemodialysis in terms of their satisfaction with their current sexual activity.

With respect to financial status, it is interesting to note that despite the relatively low income of patients with end stage renal disease (ESRD), patients are quite satisfied with their standard of living (Chapter 14). CPD patients ranked highest and in-center hemodialysis patients ranked lowest in terms of satisfaction with their standard of living. ESRD patients are somewhat less satisfied with their savings and investments. Again, CPD patients are most satisfied with their savings and investments. Transplant patients, in contrast, are least satisfied with their savings and investments. The observed difference in satisfaction with standard of living across modalities is statistically significant. The observed difference in satisfaction with savings and investments, however, is not significant.

The final two quality of life indicators reflect patients' feelings about their present life (hard versus easy, tied down versus free). As can be seen in Table 7-4, there is not much variation across modalities in terms of the extent to which patients consider their lives to be hard or easy. Although not statistically significant, on the average, transplant patients consider their lives to be easier and in-center hemodialysis patients harder than the other patient groups. With respect to feeling tied down or free, a statistically significant difference across modalities is observed. Home hemodialysis patients consider themselves most tied down, and transplant patients consider themselves most free.

In summary, of the 10 additional quality of life indicators, statistically significant differences across treatment modalities were observed for only five variables. With the exception of satisfaction with standard of living (in which CPD patients ranked highest), transplant patients ranked highest with respect to each of these quality of life indicators. It should be noted, however, that the analyses presented here do not control for differences in the characteristics of the various patient groups (i.e., case-mix differences).

Additional analyses are required to determine if the observed differences in quality of life indicators persist after controlling for case-mix differences, although in Chapter 6 we have shown that even after patient case-mix variables have been controlled, statistically significant differences in quality of life persist. It should also be noted that the analysis of variance tests presented here does not indicate which pairs of modality means are significantly different from each other (Glass et al., 1970), but only that the mean scores between at least two modalities are sufficiently different to make the overall analysis of variance test statistic significant.

Table 7-4

Patient groups scoring best and worst on quality of life indicators

Quality of life indicator	Best	Worst
General Well-Being Index	Home hemodialysis	CPD
Positive Affect Scale[1]	Transplant	In-center hemodialysis
Negative Affect Scale	Home hemodialysis	Transplant
Affect Balance Scale[1]	Transplant	In-center hemodialysis
General life satisfaction	Transplant	CPD/In-center hemodialysis
Satisfaction with sex life[1]	Transplant	CPD
Satisfaction with standard of living[1]	CPD	In-center hemodialysis
Satisfaction with savings and investments	CPD	Transplant
Feeling about present life (hard, easy)	Transplant	In-center hemodialysis
Feeling about present life (tied down, free)[1]	Transplant	Home hemodialysis

[1] Differences across the four patient groups are significant at the .05 level.

NOTE: CPD is continuous peritoneal dialysis.

Comparisons with general population

As noted in Chapter 6, most studies of patients with end stage renal disease have failed to include comparison groups such as nondialyzed renal patients, patients with other chronic diseases, or the general population (Osberg et al., 1980; Yanagida et al., 1979). In this study, use of standard measures of variables permits comparisons with the general population for estimates of 7 of the 10 variables of interest. These include the Positive Affect Scale, the Negative Affect Scale, and the Affect Balance Scale (Bradburn, 1969), as well as satisfaction with standard of living, satisfaction with savings and investments, feelings about life (easy, hard) and feeling about life (tied down, free).

A comparison is made in Table 7-5 of patients with end stage renal disease (ESRD) and the general population in terms of these seven quality of life indicators. In general, the unadjusted scale scores for ESRD patients and for the general population are not substantially different. As measured by the Positive Affect Scale, Negative Affect Scale, and Affect Balance Scale, the quality of life for ESRD patients is only slightly lower than for the general population. For other variables, including satisfaction with savings and investments, satisfaction with standard of living, and feelings about life (hard versus easy), ESRD patients rated their quality of life slightly higher than the general population. Only

Table 7-5

Unadjusted mean scores on quality of life indicators for all end stage renal disease treatment modality groups compared with the general population

Quality of life indicator	General population	All modalities	Home hemodialysis	In-center hemodialysis	CPD	Transplant
	Unadjusted mean scores					
Positive Affect Scale	3.10	3.01	3.21	2.62	2.90	3.60
Negative Affect Scale	1.60	1.80	1.70	1.82	1.86	1.93
Affect Balance Scale	5.60	5.34	5.59	4.95	5.22	5.81
Satisfaction with standard of living	5.31	5.44	5.59	5.22	5.70	5.49
Satisfaction with savings and investments	4.27	4.51	4.57	4.45	4.81	4.35
Feeling about life (hard, easy)	4.43	4.49	4.50	4.40	4.55	4.64
Feeling about life (tied down, free)	5.31	4.43	4.01	4.34	4.50	5.41

NOTE: CPD is continuous peritoneal dialysis.

with respect to their feelings about life (tied down versus free) was a larger difference observed. Not surprisingly, except for transplant patients, ESRD patients considered themselves to be more tied down than did the general population.

Discussion

The results of these analyses show that, in general, transplant patients report a higher quality of life according to several subjective indicators of life quality than patients on other treatment modalities. This is consistent with the results presented in Chapter 6. The results also show, once again, that when compared with the general population, patients with end stage renal disease (ESRD) rate their subjective quality of life similarly. This is quite contrary to other reports in the published literature that suggest that ESRD patients either have a low quality of life or are at least discontented with their life circumstances (Abram et al., 1971; Goldstein et al., 1971; McKegney et al., 1971; Penn et al., 1971).

The results of this analysis once again underscore the ability of ESRD patients to adapt to very adverse life circumstances (Johnson et al., 1982; Simmons et al., 1977). Patients seem quite capable of revising their life expectations and, subsequently, come to expect less and to feel better off than they probably are from an objective point of view.

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Chapter 8.
Patient treatment preferences

Introduction

The number of end stage renal disease (ESRD) patients in the United States continues to increase. Over 80,000 patients now are on some form of dialysis or have a functioning transplant. Even though successful transplantation undeniably offers the highest quality of life (Evans et al., 1983; 1984; Flechner et al., 1983; Gutman et al., 1981; Guttmann, 1979; Johnson et al., 1982; Kaplan DeNour et al., 1980; Naish, 1979; Poznanski et al., 1978; Simmons et al., 1977) and is the preferred modality of treatment for selected patients, donor availability remains a significant problem that restricts the use of transplantation (Bart et al., 1981; Russell et al., 1979; van der Vleit et al., 1983).

The National Kidney Dialysis and Kidney Transplantation Study and other studies have shown that patients on home hemodialysis have a higher rehabilitation rate and a more acceptable quality of life than those on other forms of dialysis, suggesting that when transplantation is not possible, patients are likely to derive the greatest benefits from home hemodialysis (Gurland et al., 1979; McGeown, 1979). Unfortunately, for many reasons, some patients are not suited for home hemodialysis (Lowrie, 1981; Lowrie and Hampers, 1981; 1982) and, as a result, various forms of peritoneal dialysis have evolved to treat diabetic patients and those with blood access problems (Diaz-Buxo et al., 1981; Nakagawa et al., 1981; Evans et al., 1981; Roxe et al., 1981; Popovich et al., 1978; Nolph et al., 1980; Johnson, 1981; Council on Scientific Affairs, 1982; Amair et al., 1982; Atkins et al., 1981). Despite innovations in dialytic therapy, however, a significant number, perhaps the majority of ESRD patients, are not candidates for any treatment except in-center hemodialysis, making this the "default" modality. In-center patients generally are thought to be sicker than other ESRD patients, having a more severe case-mix (Evans et al., 1983; Lowrie, 1981; Gardner, 1981; Eggers, 1982; Held et al., 1981; 1982; Kirsch et al., 1976).

The aim of this chapter is to determine to what extent ESRD patients viewed transplantation as the treatment of choice for renal failure. In particular, it is important to determine if patients with multiple modality experience and those who had a previously failed graft consider transplantation to be the most preferred treatment modality. No previous large-scale multicenter studies have examined patient preferences for treatment.

Materials and methods

Patients

All 859 patients who participated in the National Kidney Dialysis and Kidney Transplantation Study were considered eligible for this analysis. All patients were grouped according to their current treatment modality—home hemodialysis (N=287), in-center hemodialysis (N=347), continuous peritoneal dialysis (N=81), and transplantation (N=144). The characteristics of these patients have been described in Chapter 5.

Data sources

Data were obtained from patients, medical records, and from a health care professional familiar with each patient. Information on sociodemographic and medical variables and treatment modality preferences was obtained from each patient during a 90-minute personal interview.

Variables

Patients were asked detailed questions about their past treatment history and their preference for various treatment modalities regardless of whether or not they had previously experienced these. Among the questions asked were the following:

- What kinds of treatment have you been on?
- Do you want to stay on continuous peritoneal dialysis, home hemodialysis, or in-center hemodialysis, or would you prefer to be on another kind of treatment?
- Do you prefer your kidney transplant to other kinds of treatment you have had?
- What type of treatment would you prefer to be on?

Each patient's current treatment modality was established prior to interview and verified at the time of the interview.

Results

Preference by current treatment modality

A cross-tabulation of patient treatment modality preferences according to their current treatment is shown in Table 8-1. Clearly all patient groups prefer their current treatment modality over all other modalities, and all transplant patients prefer transplantation to any other modality. In-center hemodialysis patients prefer their modality least, and only one home hemodialysis patient preferred in-center hemodialysis. Patients on continuous peritoneal dialysis (CPD) appear to find their modality reasonably acceptable, because only 8.6 percent prefer an alternative modality. Finally, of all patients preferring an alternative modality, the majority found transplantation most preferable. In short, transplantation was the most popular treatment modailty.

Patient treatment modality experience

As shown in Table 8-2, most patients have been on several treatment modalities, suggesting that the preferences described are based on actual patient

Table 8-1

Percent distribution of patients with end stage renal disease, by treatment modality preference and current treatment modality

Current treatment modality	Number of cases	Total	Treatment modality preferences: Home hemodialysis	In-center hemodialysis	CPD	Transplant	Home intermittent peritoneal dialysis	In-center intermittent peritoneal dialysis
			Percent distribution					
Home hemodialysis	282	100.0	80.1	0.4	3.9	15.6	0.0	0.0
In-center hemodialysis	338	100.0	6.5	76.9	3.3	13.0	0.3	0.0
CPD	81	100.0	1.2	0.0	91.4	7.4	0.0	0.0
Transplantation	142	100.0	0.0	0.0	0.0	100.0	0.0	0.0

NOTE: CPD is continuous peritoneal dialysis.

experience and are not hypothetical. Transplant and CPD patients have been on the most treatment modalities, an average of 2.3 each, and in-center hemodialysis patients have the least modality experience (1.3 modalities). For some end stage renal disease patients with blood access problems, CPD may be regarded as their sole dialysis option. This may be the reason why 38.8 percent of the CPD patients have been on three or more modalities and why 12.5 percent have been on four or more modalities. Both the persistence and aggressiveness of transplant patients in receiving their treatment of choice may account for their experience with multiple treatment modalities—29.9 percent have been on three or more modalities, but only 3.5 percent have been on four or more modalities.

Across all dialysis modalities, the percent of patients that had a previous transplant was similar—13.3 percent to 19.6 percent. Not surprisingly, the vast majority of all patients have previously been on in-center hemodialysis because this is often a patient's first treatment modality. The results also suggest that there is basis for the view that home hemodialysis patients are good candidates for transplantation. Likewise, the results suggest that home hemodialysis patients are good candidates for CPD, although probably for different reasons than in-center hemodialysis patients. Neither in-center dialysis nor home intermittent peritoneal dialysis (IPD) was particularly prevalent among these patients, although there is evidence that many in-center IPD patients have shifted to CPD, presumably to minimize time, travel, and activity constraints, as well as because CPD provides better dialysis than IPD.

Preference by previous treatment modality

Detailed comparisons have been made of patients with each of the following exclusive modality experiences:

- Home hemodialysis only.
- In-center hemodialysis only.
- Both in-center and home hemodialysis only.
- Both in-center and home hemodialysis with other treatment modality experience.

As shown in Table 8-3, these preferences have been broken down by current treatment modality. Patients who have experienced both home and in-center hemodialysis but who have been transplanted or are currently on CPD prefer their current treatment modality. Similarly, patients who have only been on home hemodialysis or in-center hemodialysis prefer their current modality. These results are consistent with those presented above.

Of the patients who had been on both in-center hemodialysis and home hemodialysis, but no other modalities, current home hemodialysis patients were more likely to prefer home hemodialysis to in-center hemodialysis. Only 0.7 percent of current home hemodialysis patients expressed a preference for in-center hemodialysis. Of current in-center hemodialysis patients who had only been on both hemodialysis modalities, 18.8 percent expressed a preference for home hemodialysis.

Only 19 CPD patients had been on home and in-center hemodialysis as well as other treatment modalities. Of these patients, only one (5.3 percent) preferred home hemodialysis, and none preferred in-center hemodialysis or transplantation to CPD. Similarly, there were only 18 patients in the sample who had been on CPD in the past and who were not currently on this modality (not tabled). Of these, 3 had functioning transplants, 5 were on home hemodialysis, and 10 were on in-center hemodialysis. Only two of these patients indicated that they preferred CPD to their current modality. The tenor of this finding was general across all treatment modalities, namely, few patients who had been on a modality in the past and who were not on it currently preferred the previous modality. The exception was patients who had a previous failed transplant experience.

Patients who had a failed transplant constituted an interesting group, and they were subjected to further analysis. As shown in Table 8-4, all 20 patients who had previous failed transplants and who were retransplanted preferred transplantation to other modalities. Of patients who had failed transplants and were on home hemodialysis currently, 32.7 percent preferred a transplant. Of current in-center hemodialysis patients with a failed transplant, 28.9 percent preferred a transplant. However, of the current CPD patients who had a failed transplant, only 14.3 percent preferred a transplant. Nevertheless, as shown in Table 8-4, patients who had a previously failed transplant generally were

Table 8-2

Number and percent of patients with end stage renal disease, by past treatment modality experience and current treatment modality

Current treatment modality	Past treatment modality experience							Patients on		
	Total number of cases	Home hemodialysis	In-center hemodialysis	CPD	Transplant	Home intermittent peritoneal dialysis	In-center intermittent peritoneal dialysis	Mean number different modalities	3 or more modalities	4 or more modalities
					Percent of patients					
Home hemodialysis	285	100.0	71.2	1.8	19.6	.7	4.2	2.0	18.2	1.4
In-center hemodialysis	346	8.1	100.0	2.9	13.3	1.7	6.4	1.3	5.8	.6
CPD	80	35.0	55.0	100.0	17.5	3.8	15.0	2.3	38.8	12.5
Transplantation	144	31.9	84.7	2.1	[1]100.0	2.8	11.1	2.3	29.9	3.5

[1] 13.9 percent of the current transplant patients had a previous failed transplant.

NOTE: CPD is continuous peritoneal dialysis.

Table 8-3

Number and percent distribution of patients with end stage renal disease, by treatment modality preferences of patients who have been on both in-center and home hemodialysis and current treatment modality

Current treatment modality	Total cases	Home hemodialysis	In-center hemodialysis	CPD	Transplant
		Treatment preference			
		Percent distribution			
Home hemodialysis					
Home only	63	84.1	0.0	4.8	11.1
Home and in-center only	149	84.6	0.7	3.4	11.4
Home and in-center with other modality experience	50	60.0	0.0	4.0	36.0
In-center hemodialysis					
In-center only	250	5.2	78.8	3.6	12.4
Home and in-center only	16	18.8	81.3	0.0	0.0
Home and in-center with other modality experience	11	0.0	72.7	0.0	27.3
CPD					
Home and in-center with other modality experience	19	5.3	0.0	94.7	0.0
Transplant					
Home and in-center with other modality experience	28	0.0	0.0	0.0	100.0

NOTE: CPD is continuous peritoneal dialysis.

Table 8-4

Number and percent distribution of patients with end stage renal disease, by treatment modality preferences of patients who previously had a failed graft and current treatment modality

Current treatment modality	Total cases	Home hemodialysis	In-center hemodialysis	CPD	Transplant
		Treatment modality preferences			
		Percent distribution			
Home hemodialysis	55	65.5	0.0	1.8	32.7
In-center hemodialysis	45	6.7	60.0	4.4	28.9
CPD	14	0.0	0.0	85.7	14.3
Transplantation	[1]20	0.0	0.0	0.0	100.0

[1] These 20 patients had functioning grafts but had had a failure in the past. They currently prefer transplantation, and because they had the transplant, it is assumed that they preferred it before the successful transplantation.

NOTE: CPD is continuous peritoneal dialysis.

more likely to prefer their current modality over any of the previous modalities they had been on.

Sociodemographic differences in preference trends

Detailed analyses were undertaken to examine the relationship of age, sex, race, and education to patient preferences for treatment modalities. Each treatment modality was assessed individually. Among current home hemodialysis patients, older patients were more likely to prefer staying on home hemodialysis, and younger patients were more likely to prefer transplantation. Neither sex nor race distinguished patient preferences. In some cases, education was found to be associated with patient modality preferences. In particular, the more educated in-center hemodialysis patients were more likely to prefer an alternative treatment modality. Consistently, more educated patients, regardless of their current treatment, preferred transplantation to other modalities.

Discussion

The results indicate that most end stage renal disease (ESRD) patients prefer their current treatment modality over others they have heard about or experienced. Patients generally perceived transplantation as the most acceptable treatment modality. Even among patients who had had a previous failed graft, transplantation remained the preferred treatment. Finally, among all treatment modalities, in-center hemodialysis appeared to be the least prefered by patients, although it constitutes the default modality for many.

The issues raised by these results are far more complex than depicted by the analyses. Only patient preferences have been examined, and no attempt has been made to provide a decision analysis framework within which to analyze and interpret the results (Deber et al., 1982; McNeil et al., 1975; Weinstein et al., 1980). It is assumed that patient preference is a key element in a physician's assignment to, or encouragement of, a patient to undergo a particular treatment (Smith et al., 1983). Yet, it must also be recognized that numerous other factors influence patient preference, including dialysis and transplant center-specific characteristics, the patient's medical condition and social situation, the patient's experience with previous treatment modalities, both patient's and physician's expectations about success, and various patient characteristics that may serve as contraindications for some treatment modalities.

The high cost of treating ESRD—$1.7 billion in 1983—has made it imperative that the Federal Government seek ways to reduce total program expenditures. One way to accomplish this is to make greater use of less expensive treatment modalities such as transplantation and home hemodialysis (Stange et al., 1978; Roberts et al., 1980; Iglehart, 1982). Yet, cost containment initiatives must be properly integrated with a concern to maximize patient outcomes. To accomplish this integration, greater attention must be focused on patient knowledge about, satisfaction with, and preferences for the available treatment modalities. The results of empirical studies linking treatment modalities with patient outcomes must be widely available in order to insure that patients are encouraged to utilize that treatment modality from which they are likely to derive the greatest benefit. In short, the objective is to integrate treatment modality prescription and patient outcome goals with cost containment objectives.

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Quality of care

Chapter 9.
Hospitalization

Introduction

Quality of care is a seldom discussed yet primary consideration in the treatment of patients with chronic renal failure. In principle, however, the concept of quality of care remains elusive, although patient outcomes are increasingly used as alternatives to structure and process measures (Donabedian, 1966; 1969; 1978; Starfield, 1974; Brook et al., 1976; Wennberg et al., 1980; Williamson et al., 1982). Hospitalization, for example, is one possible quality of care indicator that is relevant to the end stage renal disease (ESRD) patient experience (Eggers, 1982).

Unfortunately, even after suitable quality of care indicators can be agreed on, an examination of outcomes is complicated by several factors that include the relationship between outcomes and patient characteristics. Several studies, including the National Kidney Dialysis and Kidney Transplantation Study, have now documented substantial case-mix differences among patients on dialysis and transplantation. For example, as demonstrated in Chapter 5, in-center hemodialysis patients are generally older and sicker than transplant recipients. Thus, quality of care comparisons must take into account the nonrandom assignment of patients to treatment modalities.

It is also important to recognize, however, that case-mix may not only indirectly affect outcomes such as hospitalization through treatment modality but may also directly affect hospitalization independent of modality. For example, comorbidity may preclude a patient from transplantation but may also directly affect hospitalization. In summary, case-mix variables, such as age, sex, and race, as well as various clinical factors such as comorbidity, can both directly and indirectly affect hospitalization (Figure 6-1). In the analysis of the hospitalization experience of ESRD patients, it is extremely important that these case-mix differences are controlled statistically.

The objective of this Chapter is to examine differences in hospitalization over a 12-month period among ESRD patients on four treatment modalities, taking patient case-mix differences into account. In addition, the data are analyzed separately for patients who had been on their current treatment modality for less than 1 year and those who had been on their current treatment modality for 1 year or more. It is assumed that patients who had not been on a given treatment modality for at least 1 year were likely to be less medically stable than patients who had greater modality experience.

Data and methods

Patient groups

All patients who participated in the National Kidney Dialysis and Kidney Transplantation Study were eligible for this analysis, provided, of course, they were able to provide information on hospitalization and had consented to have their medical records reviewed.

Variables and data sources

The following three major categories of variables were used in the analysis:

- Sociodemographic case-mix variables, such as age, sex, race, and education.
- Medical case-mix variables, including primary diagnosis, comorbidity, and length of time on the current treatment modality.
- Number of times hospitalized and number of nights hospitalized during the previous 12-month period.

Cross-tabulations of the sociodemographic and medical case-mix variables by treatment modality have been provided in Chapter 5.

With respect to primary diagnosis, a dichotomous variable was used to denote whether the primary diagnosis of the patient's renal disease was diabetes or some other condition. An index of comorbidity, described in Chapter 5, was used to measure current health status. The third medical variable of clinical significance—length of time on current treatment modality—reflects whether patients had been on their current treatment modality for less than 1 year or for 1 year or more.

Finally, the following four measures of hospitalization were incorporated in the analysis:

- Number of nights hospitalized in the past year (mean for all patients).
- Percent of patients who had been in the hospital (overnight) one or more times during the past year.
- Number of times hospitalized overnight in the past year (mean for all patients hospitalized).
- Mean length of stay per hospitalization (mean for all patients hospitalized).

Socioeconomic and clinical data, as well as data concerning hospitalizations, were obtained directly from the patient during a personal interview. With written consent, additional clinical data (including information on hospitalizations) were abstracted from the patient's medical record. For purposes of analysis, data on hospitalizations obtained from the medical record were used only if the data recorded during the patient interview were incomplete.

Statistical methods

One-way analysis of variance was used to test the significance of differences in hospitalization across modalities (Glass and Stanley, 1970). Multiple classification analysis, a variant of dummy variable multiple regression and a type of covariance analysis, was used

Table 9-1

Hospitalization of patients with end stage renal disease, by treatment modality: Unadjusted and case-mix adjusted percents and mean scores

Item	All treatment modalities	Home hemodialysis	In-center hemodialysis	CPD	Transplant	p-value	Home hemodialysis	In-center hemodialysis	CPD	Transplant	p-value
	Unadjusted						Adjusted				
Mean number of nights hospitalized in past 12 months	12.2	8.3	13.8	20.1	11.4	.0000	9.0	13.0	18.1	13.2	.004
Percent of patients hospitalized 1 or more times	63.7	55.2	69.4	85.2	54.9	.0000	57.4	66.8	77.6	60.1	.004
Mean number of times hospitalized for those hospitalized at least once	2.5	2.4	2.5	3.2	2.1	.0078	2.4	2.6	3.0	2.0	.045
Mean length of stay in days for those hospitalized at least once	8.0	6.6	8.1	7.7	10.7	.0113	6.8	7.9	7.4	11.0	.017

NOTE: CPD is continuous peritoneal dialysis.

to determine whether modality differences in hospitalization persisted once initial patient case-mix differences were statistically held constant (Sonquist, 1970; Andrews et al, 1973; Nie et al., 1975).

Results

Differences across modalities

A summary of the variation in hospitalization in the last 12 months by treatment modality for all end stage renal disease patients included in the study is given in Table 9-1. Differences were first examined across the four modalities, and then multiple-classification analysis was used to examine differences after patient case mix was considered (e.g., sociodemographic and medical characteristics). Both unadjusted and adjusted mean scores are shown in Table 9-1.

Four different variables are shown. The first is the mean number of nights that all patients on a given modality had been hospitalized in the last year. The average number of nights hospitalized across all modalities is 12.2; however, there is considerable variation in the number of nights hospitalized across treatment modalities. The raw or unadjusted scores indicate that home hemodialysis patients spent the least number of nights hospitalized, and patients on continuous peritoneal dialysis (CPD) spent the most nights in the hospital.

The observed variation in the number of nights hospitalized can, however, reflect differences in several other variables. A particular modality could exhibit a higher mean number of nights hospitalized for one or more of the following reasons:

- The group had a higher percent of patients hospitalized one or more times.
- Those patients hospitalized were hospitalized more frequently.
- When hospitalized, patients stayed in the hospital for a longer period of time.

Each of these three variables was examined for each treatment modality.

Nearly two-thirds (63.7 percent) of all patients reported having been hospitalized at least once during the past 12 months. With respect to hospitalization rates, the four modalities can be ranked from least to greatest as follows: transplant, home hemodialysis, in-center hemodialysis, and CPD. Similarly, of those patients hospitalized, transplant patients had been hospitalized on the average of 2.1 times, whereas CPD patients had been hospitalized on the average of 3.2 times (the average for all modality groups was 2.5 times). A very different pattern emerges, however, in terms of mean length of stay. Transplant patients, on the average, were hospitalized longer than the other patient groups. Home hemodialysis patients had the shortest average hospital stay, with in-center hemodialysis patients and CPD patients falling closer to the mean for all patients.

Having observed statistically significant differences in hospitalizations across treatment modalities, multiple-classification analysis was then used to determine if such differences persist after controlling for the case-mix differences among the various patient groups. In addition to treatment modality, the four sociodemographic variables and the three clinical variables described above were included in the analysis.

Even after the patient case-mix differences are taken into account, treatment modality remains a significant variable underlying the observed differences in hospitalization (Table 9-1). Moreover, in examining the case-mix adjusted scores, the same general patterns persist. On the average, home hemodialysis patients are hospitalized the fewest number of nights, and CPD patients spend the greatest number of nights in the hospital.

Furthermore, the analysis shows that in addition to treatment modality, comorbidity and time on current treatment modality are important factors underlying the observed differences in hospitalization. Other factors such as age, sex, race, education, and diabetes were not shown to be important.

Differences by time on current modality

The analyses presented above revealed a relationship between hospitalization and the length of time that patients had been on their current treatment modality. Below, hospitalization is examined separately for patients based on whether they had been on their current treatment modality for less than 1 year or for 1 year or more.

Table 9-2 presents analyses of hospital use in the last 12 months by treatment modality and length of time on current modality. In the case of patients who had been on their current modality for less than 1 year, the case-mix adjusted scores reveal that treatment modality remains a significant factor underlying the observed variation in three of the four hospitalization variables. In general, home hemodialysis patients had the lowest and transplant patients had the highest rate of hospitalization. This difference is perhaps most striking in the case of the mean length-of-stay variable. Moreover, treatment modality was the only variable that was significant in explaining the observed variation in hospitalization among patients who had been on their current modality for less than 1 year.

Among patients who had been on their current modality for 1 year or more, an entirely different pattern emerges. For all modalities, hospitalization was less among patients who had been on their current modality for 1 year or more compared with patients who had been on their current modality for less than 1 year (Table 9-2). In addition, after taking case-mix differences into account, treatment modality is not a significant factor underlying hospitalization among end stage renal disease patients. Among these patients, transplant patients no longer exhibit the highest rate of hospitalization. Finally, the analyses show that comorbidity rather than treatment modality is the one factor that explains the observed variation in hospitalization among patients who had been on their current modality for 1 year or more (with age being significant only in the case of the mean number of nights hospitalized for all patients).

Table 9-2

Hospitalization of patients with end stage renal disease, by treatment modality and length of time on current modality: Case-mix adjusted percents and mean scores

	Less than 1 year						1 year or more					
Item	All treatment modalities	Home hemodialysis	In-center hemodialysis	CPD	Transplant	p-value	All treatment modalities	Home hemodialysis	In-center hemodialysis	CPD	Transplant	p-value
Mean number of nights hospitalized in past 12 months	18.9	10.6	18.3	24.5	28.7	.001	10.1	8.3	11.4	14.8	9.5	.225
Percent of patients hospitalized 1 or more times	84.0	63.7	91.3	92.2	96.5	.001	57.3	55.2	59.1	75.6	51.2	.067
Mean number of times hospitalized for those hospitalized at least once	2.8	2.5	2.9	3.3	2.3	.145	2.4	2.4	2.5	2.7	2.0	.452
Mean length of stay in days for those hospitalized at least once	9.3	7.3	7.5	8.1	18.1	.001	7.4	6.5	8.0	7.6	7.7	.615

NOTE: CPD is continuous peritoneal dialysis.

Pairwise comparisons of modality differences

In the preceding section, statistically significant differences in hospitalization were observed across treatment modalities among patients who had been on their current treatment modality for less than 1 year. In contrast, among patients who had been on their current treatment modality for 1 year of more, statistically significant differences across treatment modalities were not observed. The analyses presented thus far, however, do not indicate which pairs of modality means are significantly different from each other, but they do show that the mean scores between at least two modalities are sufficiently different to make the overall test statistic significant.

To gain a better understanding of the observed modality differences, pairwise multiple-classification analyses (Sonquist, 1970; Andrews et al., 1973; Nie et al., 1975) were performed on the four hospitalization variables (to take patient case-mix differences into account). These pairwise comparisons were made for all patients, as well as separately for those patients on their current modality for less than 1 year and for those patients on their current modality for 1 year or more.

Pairwise modality differences that are significant ($p \leq .05$) for each of the four hospitalization variables are shown in Table 9-3. Differences in the mean number of nights hospitalized in the last 12 months reflect the fact that home hemodialysis patients differ from those on the other three treatment modalities. Among patients who had been on their current modality for less than 1 year, this same pattern is apparent. (In addition, in-center hemodialysis and transplant patients were shown to be significantly different.) In contrast, among patients who had been on their current modality for 1 year or more, only home hemodialysis and patients on continuous peritoneal dialysis (CPD) were found to be statistically different.

Similarly, with respect to the percent of patients hospitalized one or more times, home hemodialysis patients appear to differ most from those on the other treatment modalities. Among all patients, regardless of time on modality, home hemodialysis patients were found to be different from both in-center hemodialysis and CPD patients. Among patients on their current modality for less than 1 year, home hemodialysis patients differed significantly from those in the other three patient groups. Among patients on their current treatment modality for 1 year or more, CPD patients differed significantly from both home hemodialysis and transplant patients.

Few pairwise differences were observed in the mean number of times hospitalized for those patients hospitalized at least once. Among all patients, the only statistically significant pairwise difference was observed between CPD and transplant patients. This difference was also observed among patients on their current treatment modality for 1 year or more. However, among patients on their current treatment modality for less than 1 year, no pairwise differences were statistically significant.

Finally, in terms of mean length of stay, transplant patients differ most from the other patient groups. Among all patients, transplant patients differed significantly from the home hemodialysis and CPD patients. Similarly, among patients on their current treatment modality for less than 1 year, transplant patients were significantly different from the in-center hemodialysis and CPD patients. Among patients on their current modality for 1 year or more, however, no pairwise differences were statistically significant.

Table 9-3

Significance of treatment modality with respect to hospitalization: Pairwise comparisons of modalities

Comparison	Mean number of nights hospitalized in past 12 months	Percent of patients hospitalized 1 or more times	Mean number of times hospitalized for those hospitalized at least once	Mean length of stay in days for those hospitalized at least once
All patients				
Home with in-center	Yes	Yes	No	No
Home with CPD	Yes	Yes	No	No
Home with transplant	Yes	No	No	Yes
In-center with CPD	No	No	No	No
In-center with transplant	No	No	No	No
CPD with transplant	No	No	Yes	Yes
All four modalities	Yes	Yes	Yes	Yes
Patients on current modality less than 1 year				
Home with in-center	Yes	Yes	No	No
Home with CPD	Yes	Yes	No	No
Home with transplant	Yes	Yes	No	No
In-center with CPD	No	No	No	No
In-center with transplant	Yes	No	No	Yes
CPD with transplant	No	No	No	Yes
All four modalities	Yes	Yes	No	Yes
Patients on current modality 1 year or more				
Home with in-center	No	No	No	No
Home with CPD	Yes	Yes	No	No
Home with transplant	No	No	No	No
In-center with CPD	No	No	No	No
In-center with transplant	No	No	No	No
CPD with transplant	No	Yes	Yes	No
All four modalities	No	No	No	No

NOTES: Yes is p-value less than or equal to .05. No is p-value greater than .05. CPD is continuous peritoneal dialysis.

Discussion

The results of these analyses have shown that, even after patient case-mix differences are taken into account, significant differences in hospitalization exist across the four treatment modalities. The analyses further indicate that medical and clinical factors, in particular comorbidity and length of time on current treatment modality, were more important than sociodemographic factors in explaining the observed variation in hospitalization across modalities.

A more detailed examination of the importance of length of time on current treatment modality was then performed. Two groups of patients were examined separately—those who had been on their current treatment modality for less than 1 year and those who had been on their current modality for 1 year or more. For each of the four treatment modalities, those patients who had been on their current treatment modality for less than 1 year experienced greater hospitalization than patients who had been on their current treatment modality for 1 year or more. For some modalities, such as transplant patients, this difference was very large. In fact, transplant patients, who ranked highest in terms of nights hospitalized among patients on their current modality for less than 1 year, were among the lowest in terms of nights hospitalized among patients on their current treatment modality for 1 year or more. Indeed, among patients on their current modality for less than 1 year, even after taking patient case-mix into account, treatment modality remained a significant factor underlying the observed variation in three of the four hospitalization variables examined. However, among patients on their current modality for 1 year or more, comorbidity, not treatment modality, was the important factor underlying the observed differences in hospitalization.

Thus, differences in hospitalization across treatment modalities largely reflect differences in the first 12 months on a given treatment modality. Once patients have been on a modality for 1 year or more, few differences in hospitalization are observed across modalities. Moreover, the modality differences observed among patients who had been on their current modality for less than 1 year reflect a low hospitalization rate among home hemodialysis patients and a very high rate among transplant patients (presumably reflecting the long hospitalization associated with the transplant procedure). In-center hemodialysis and CPD patients did not differ statistically with respect to any of the hospitalization variables.

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Chapter 10.
Extrarenal complications of kidney transplant

Introduction

Considerable evidence has now been accumulated that clearly indicates that kidney transplantation is superior to kidney dialysis in the treatment of end stage renal disease (Belzer et al., 1983; Guttmann, 1979; Hamburger et al., 1981; Morris, 1979; Standards Committee for the American Society of Transplant Surgeons, 1981; Wood, 1983). Both medically and socially, transplantation has an edge. From a clinical perspective, transplant recipients, on the whole, are an easier group to manage. On the social side, transplant recipients, almost without fail, report a quality of life that is superior to that of dialysis patients. The only occasion for which this is not true is in circumstances where the transplant recipient experiences graft failure and ultimately returns to dialysis. The experience of returning to dialysis after a period of time with a stable graft is clearly devastating to many patients. Therefore, to present a more balanced picture of the "success" of transplantation, in comparison with other treatment modalities for end stage renal disease, it seems reasonable to reflect on the problems of transplantation. As most nephrologists freely admit, and many transplant surgeons would prefer to ignore, kidney transplantation, although the optimal treatment modality, is by no means the panacea that many patients believe it to be. For this reason, this chapter is devoted to the "darker" side of transplantation—the complications that inevitably arise. In a discussion of quality of life, it seems particularly appropriate to consider these.

It is well recognized that numerous long-term and short-term complications beset organ transplant recipients. These complications, reviewed thoroughly by Crosnier (1981) and Tilney and Lazarus (1982a), include delayed healing and disruption of the site of incision; hemorrhage and perirenal abcess; urinary collection; development of lymphocele; vascular problems such as arterial stenosis (Lacombe, 1975; Tilney, 1982; Tilney and Lazarus, 1982b); urinary tract disorders that include reflux, stenosis, urinary fistulas; and ureteral obstructions (Pfeffermann et al., 1976; Schiff, et al., 1976; Caralps et al., 1977). In addition, there is a whole host of infectious complications—bacterial, viral, and fungal (O'Brien, 1982). Pulmonary infections are not uncommon. Various hepatic complications such as hepatitis, peliosis hepatis, and idiopathic portal hypertension all appear to have some association with transplantation. Bone disorders remain a very significant problem, as many patients have difficulties associated with hyperparathyroidism, asceptic osteonecrosis, and various other complications affecting the skeleton and joints (Crosnier, 1981; Murray, 1973; Woods et al., 1972; Ibels et al., 1978; Crosnier and Broyer, 1979; Gottlieb et al., 1982; Kenzora et al., 1982). Cardiovascular problems may also develop; chief among these is arterial hypertension (Crosnier, 1981; Grunfeld et al., 1975; Tilney and Lazarus, 1982b). Hematologic problems are by no means rare. Some patients fail to recover normal hematocrit or secondarily develop anemia, even though renal function is normal (Roman et al., 1972). In addition to anemia, transplant recipients may develop leukopenia and thrombocytopenia, as well as polycythemia. Malignant tumors remain a source of concern (Penn, 1983; Kinlen et al., 1983; Birkeland, 1983). In large transplantation series, the incidence of malignant tumors may be between 2.0 and 7.0 percent (Crosnier, 1981; Matas et al., 1975; Sheil, 1977). Penn, in studies of de novo malignancies, estimates that the age-adjusted rate of cancer for transplant recipients is 100 times greater than that of the general population (Penn, 1974; 1978; 1979; 1981; 1982; Lanza et al., 1983). Other complications associated with organ transplantation include gastrointestinal disorders such as peptic ulcer, perforation and/or gastrointestinal hemorrhage (Crosnier et al., 1979; Tilney et al, 1982c); steroid diabetes resulting from chronic steroid administration; psychiatric disorders (Crosnier, 1981); pancreatitis (Woods et al., 1972; Karrer et al., 1982; Tilney et al., 1966; Johnson and Nabseth, 1970); and ophthalmic complications including cataract, induced by high dose steroids given during rejection episodes (Crosnier, 1981; Burns, 1982). Finally, skin lesions are also prevalent among transplant recipients and are largely the result of immunosuppressive therapy, although virus, herpes simplex, and herpes zoster may also be implicated.

The objective of the analysis that follows is to examine differences in the prevalence of extrarenal complications among patients who have experienced a failed kidney transplant and are back on kidney dialysis and patients who have functioning grafts. Few reports have specifically focused on the failed transplant experience and the complications that are associated with it.

Patients and methods

Patients

Unlike previous chapters in this report, this chapter will focus only on those patients in the study who have previously received a kidney transplant. All patients in the sample were eligible for this analysis provided they had received a kidney transplant at some point in time. These patients were then divided into two groups—those who had a graft that was currently functioning and those who had rejected a transplanted kidney and were back on dialysis. Of the patients studied, 144 had functioning grafts. Of these 144 patients, 20 patients had been retransplanted following a previous graft failure. Of the 859 patients in the sample, 116 had experienced a failed graft and were back on dialysis.

Statistical methods

The t-test and the chi-square test were used to test for overall differences in the sociodemographic and medical characteristics of the two patient groups—those with a functioning graft and those with a failed graft who returned to dialysis (Brown et al., 1977; Box et al., 1978; Armitage, 1971). In addition, the t-test was used to assess the significance of differences in the prevalence of extrarenal complications among the two patient groups.

Results

Patient characteristics

The sociodemographic characteristics of those patients who had a failed graft and those with a functioning graft are presented in Table 10-1. As shown here, the patient groups do not differ significantly. Only with regard to race do the differences approach significance. In particular, a somewhat higher proportion of black patients were found to have a failed rather than a functioning graft. This result is consistent with findings presented elsewhere that show that black patients are at a higher risk for transplant rejection than white patients are, primarily because black patients are less likely to receive living-related donor transplants.

The primary diagnosis of renal condition for both patient groups is provided in Table 10-2. Although there are some differences between the two groups in terms of diagnosis, overall, these differences are not significant (chi-square value = 10.5, p = .186). The two groups differ markedly, although not significantly, in the diagnoses of nephrosclerosis and diabetes.

Extrarenal complications

Study results as they pertain to extrarenal complications other than cancer are shown in Table 10-3. It is most noteworthy that every extrarenal complication is more prevalent in the failed graft group than in the patient group with functioning grafts. In particular, cardiovascular problems (other than angina and myocardial infarction), gastrointestinal problems, neurological problems, and musculoskeletal disorders are more serious problems for patients who have experienced a failed transplant. As indicated in Table 10-3, according to t-tests, these differences are highly significant. These results are consistent with and, therefore, confirm what has been reported in the literature.

Table 10-1

Percent distribution of transplant recipients with functioning and failed allografts, by sex and race with mean age and level of education

Characteristic	Current functioning graft (no failures)	Failed graft(s)	Test statistic	*p*-value
Age (mean)	37.6	37.8	$t = 0.14$	.8910
		Percent distribution		
Sex:				
Male	54.0	61.2	$x^2 = 0.99$	.3207
Female	46.0	38.8		
Race:				
Black	12.1	22.6	$x^2 = 5.59$	.0610
White	84.7	72.2		
Other	3.2	5.2		
Education (mean)	12.2	12.7	$t = 1.36$	.174

Table 10-2

Percent distribution of transplant recipients with functioning and failed allografts, by primary diagnosis of renal condition

Primary diagnosis	Current functioning graft (No failures)	Failed graft(s)	*t*-value	*p*-value
		Percent distribution		
Interstitial	15.7	13.4	.10	.754
Polycystic	5.0	7.1	.18	.671
Primary renal disease involving glomerular-arteriolar structures	52.1	48.2	.11	.741
Primary hypertensive renal disease	6.4	8.0	.47	.491
Nephrosclerosis	4.3	1.8	.94	.333
Systemic lupus erythematosis	1.4	0.0	.43	.512
Diabetes	7.9	5.4	.71	.399
Myeloma	0.0	0.0	N/A	N/A
Other	8.6	16.1	3.43	.064

NOTE: NA means not applicable.

Table 10-3

Percent of transplant recipients with functioning and failed allografts, by extrarenal complications

Extrarenal complications	Current functioning graft (No failures)	Failed graft(s)	*t*-value	*p*-value
		Percent		
Angina, myocardial infarction	3.3	5.2	.15	.695
Other cardiovascular problem	5.0	13.9	4.50	.034
Respiratory disease	1.7	2.6	.00	.962
Gastrointestinal problems	2.5	13.9	8.81	.003
Neurological problems, cerebrovascular accident, including stroke	0.0	9.6	9.99	.002
Musculoskeletal disorders, including bone disease	10.8	29.6	11.73	.001
Infection other than access problems or peritonitis	2.5	3.5	.00	.954
Hepatitis	4.2	7.0	.42	.516
Hematologic problems other than anemia	0.8	3.5	.91	.341
Spinal abnormality (lower back problem, arthritis)	0.0	4.3	3.45	.063

NOTE: Patients may have more than 1 condition.

To summarize these findings, the index of comorbidity described in Chapters 5 and 6 was used to describe the prevalence of extrarenal complications among the patients with functioning grafts and those with failed grafts. Based on this index, it was determined that patients with a functioning graft had an average of .32 complicating conditions, and patients who previously had a failed graft were found to have an average of .93 conditions. A t-test reveals this difference to be highly significant (t-value = 4.55, p = .000).

Discussion

The results indicate that kidney transplant recipients who have experienced a failed graft have a greater prevalence of comorbidity than recipients who have functioning grafts. In particular, although the two patient groups do not differ in terms of case-mix—that is, their age, sex, race, education, and disease diagnosis—patients who have had a failed graft are significantly more likely than patients with functioning grafts to have cardiovascular problems, neurological disorders, and musculoskeletal disorders. These findings, although a source of concern, are certainly not surprising given other published reports on extrarenal complications associated with transplantation (Crosnier, 1981; Tilney and Lazarus, 1982a).

Few renal physicians, transplant surgeons, and nephrologists alike are likely to disagree that a successful kidney transplant is the optimal form of treatment for kidney failure. It is apparent, however, that a failed graft results in a patient apparently becoming sicker than they were prior to receiving a transplant, because most transplant candidates are unlikely to have the complications that were found among the failed graft group prior to receiving their transplant. To this extent, a transplant represents a risk to the patient. If the transplant is successful, the patient is likely to do quite well, but if the graft fails, they may return to dialysis in poorer health than they were before transplantation.

Few studies have focused on the medical and social complications associated with the failed transplant experience. Focus here has been on the former, and at least six papers have focused on the latter (Johnson et al., 1982; Evans et al., 1982a; 1982b; 1982c; Garrison et al., 1983; Manninen et al. 1983). Data in these latter papers indicate that morbidity, rehabilitation, and quality of life are all poorer among failed transplant patients than among those with functioning grafts. Collectively, the data emphasize the need for more careful assessments of patients who have experienced a failed graft. It may well be that, in the already high-risk patient who can be adequately managed on dialysis (Sutherland et al., 1982), the further risks associated with a failed graft do not outweigh the benefits sought through transplantation. To this extent, risk must be assessed not only in terms of graft and patient survival but also in terms of potential complications that may affect the patient's health status adversely (Salaman, 1983).

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Disability and health status

Chapter 11. Premorbid and post-treatment functional limitations

Introduction

There are no published studies that have examined the functional limitations of end stage renal disease (ESRD) patients before and following the onset of maintenance dialysis or the receipt of a kidney transplant. Although there are several published reports concerned with the functional ability of patients following the onset of dialysis (Gombos et al., 1964; Siemsen et al., 1972; Gutman et al., 1981), the focus in most studies has been on patient survival as the most significant of clinical outcomes (Stange and Sumner, 1978; Lowrie et al., 1973; Weller et al., 1982; Krakauer, 1980; Krakauer et al., 1983).

It is generally acknowledged that the primary goal of all medical treatment is to restore the patient's health. Although in the case of chronic illness this goal is at best tenuous, return to good health is admittedly relative to the patient's condition. For the patient who is debilitated by their condition, however, an equally important goal is to restore their ability to function. Again, restoration of function is relative, with significant accomplishment being made when a patient is able to function much as they did premorbidly. Consequently, it is not surprising that patient outcomes have increasingly served as indicators of the quality of care patients receive (Brook et al., 1976; Donabedian, 1966; 1969; 1978; 1980; 1982; Evans, 1979; Starfield, 1973; 1974; Williamson, 1978). Restored functional ability is one such patient outcome, often incorporated into complex quality of care assessment models (Starfield, 1973; Brook, et al., 1976; Evans, 1979; Manninen et al., 1983).

As described by Cluff (1981), quality of life and quality of medical care both have a common objective, and that is optimal or maximal personal function. Quality of life remains a misused and allusive concept that therefore undoubtedly accounts for the fact that the results of previous studies on the quality of life of ESRD patients have not been entirely consistent. Multiple indicators of quality of life have been used, including vocational rehabilitation, physical morbidity, and sexual functioning (Wing et al., 1978; Bryan et al., 1978; Evans et al., 1981; Tews et al., 1980; Gutman et al., 1981; Procci et al., 1981; Kaplan DeNour and Shanan, 1980; Friedman et al., 1970; Beard, 1971; Bergsten et al., 1977; Poznanski et al., 1978; Levy and Wynbrandt, 1975; Simmons et al., 1977; Simmons, 1978; Sophie and Powers, 1979; Guttmann, 1979). Relying on what could be considered more or less objective indicators, it has been suggested in many of these studies that the quality of life of patients with ESRD is quite poor. The focus of more recent studies, including the National Kidney Dialysis and Kidney Transplantation Study, on the subjective aspects of quality of life (i.e., life satisfaction, well-being, psychological affect), however, provides a different perspective (Johnson et al., 1982; Evans et al., 1982d). The results of these studies (as reported in Chapters 6 and 7) reveal that the quality of life of ESRD patients, although subject to considerable variation across treatment modalities, is approximately equal to or better than that of the general population.

Discrepancies between the results of studies dealing with the subjective aspects of quality of life and those focusing on objective indictors of life quality would suggest that greater attention should be directed to the functional limitations experienced by ESRD patients because quality of life, both subjective aspects and objective indicators, could be affected by functional limitations. Moreover, even though previous studies indicate that ESRD patients are quite limited in their functional ability, the relationship between treatment modality and functional limitations is by no means clear.

Although this chapter will not address all the foregoing issues, it will provide some initial results on the premorbid and post-treatment functional limitations of patients on various ESRD treatment modalities. Also, these study results will lend a greater understanding to the relationship between functional ability and treatment modality, although as suggested above, this relationship is by no means straightforward and may be the result of patient case-mix differences or unique dialysis and transplant center factors (Evans et al., 1982c).

Methods

Patient groups

This analysis is limited to the same four patient treatment modality groups that were analyzed in Chapters 6 through 9. No redefinition of patient modality groups has been performed for this analysis. The number of patients in each group is as follows: 287 home hemodialysis patients, 347 in-center hemodialysis patients, 81 continuous peritoneal dialysis patients, and 144 transplant patients.

Variables

In addition to standard sociodemographic and medical variables (case-mix) that describe the patient sample (Chapter 5), several measures of functional limitations are considered in this analysis. The first of these is the Karnofsky Index, which has been applied to end-stage renal disease (ESRD) patients on two previous occasions (Gombos et al., 1964; Gutman et al., 1981). Mean scale scores on the Karnofsky Index have been previously included in the analysis presented in Chapter 6. In this analysis, the gross distribution of Karnofsky scores will be presented.

The Karnofsky Index, reproduced in Table 11-1, is a rating scale used to classify a patient's overall functional status (Karnofsky and Burchenal, 1949). As shown in Table 11-1, the Karnofsky Index has three alphabetic groups for classifying patients' ability to work, to carry on normal activity, and to care for themselves. These alphabetic groups are further divided into 11 categories that appear to cover all possible levels of function from completely normal to dead.

To measure specific functional impairments, a series of questions taken from the Rand Health Insurance Study (Stewart et al., 1978) were adapted to fit the unique experience of ESRD patients. There were 12 such questions. These questions, reproduced in Appendix 11-A, are formatted as follows:

> "Does your health limit the kind of vigorous activities you can do, such as running, lifting heavy objects, or participating in strenuous sports?"

If the patient's response was yes, then the following question was asked:

> "Did your health limit the kind of vigorous activities you did before you got kidney disease?"

The key to answering the second question was the point of reference "limitations the patient had before the onset of kidney disease." For some patients it is possible that this time period was confused with the time period just before the onset of treatment. The two do not necessarily coincide. It should be recalled, however, that all interviewers who administered the survey instruments to the patient attended an intensive 3-day training session during which detailed attention was given to every question in the questionnaire. In addition, each interviewer was provided with a procedures manual that they took with them when they left the training session (Evans et al., 1982a). The procedures manual contained detailed question-by-question specifications. Thus, there is little reason to believe that patients responded to the questions with the incorrect timeframe in mind.

To complement the Rand Health Insurance study questions, an additional set of questions concerning specific functional limitations was incorporated into the survey instrument. These questions, taken from the 1978 Survey of Disability and Work conducted by the Social Security Administration (Bye and Schechter, 1982), are reproduced in Appendix 11-B. It should be noted that these questions referred to only one time period—the present.

Statistical methods

It has been shown previously that patients on each of the four ESRD treatment modalities differ significantly in terms of case-mix (i.e., age, sex, race, education, primary diagnosis, and comorbidity). These differences are described in detail in Chapter 5. For purposes of the present analyses, the chi-square test was used to test for differences in functional limitations among patients on different treatment modalities (Armitage, 1971; Glass and Stanley, 1970).

Results

In Chapter 6, it has been demonstrated that despite patient case-mix differences, treatment modality consistently had a unique effect on various patient outcomes such as quality of life. Although it is acknowledged that such differences may have a unique effect on various measures of functional ability, no effort has been made here to control statistically for these variables. The evidence is overwhelming that the case-mix variables will not eliminate the unique modality effect on both general and specific functional limitations experienced by patients with chronic renal failure.

Table 11-1
The Karnofsky Index

Class	Condition	Group	Percent of performance status	Comments
I	Able to carry on normal activity and to work. No special care is needed.	A	100	Normal. No complaints. No evidence of disease.
		B	90	Able to carry on normal activity. Minor signs or symptoms of disease.
		C	80	Normal activity with effort. Some signs or symptoms of disease.
II	Unable to work. Able to live at home, care for most personal needs. A varying degree of assistance is needed.	A	70	Cares for self. Unable to carry on normal activity or to do active work.
		B	60	Requires occasional assistance, but is able to care for most of his needs.
		C	50	Requires considerable assistance and frequent medical care.
III	Unable to care for self. Requires equivalent of institutional or hospital care. Disease may be progressing rapidly.	A	40	Disabled. Requires special care and assistance.
		B	30	Severely disabled. Hospitalization is indicated although death not imminent.
			20	Hospitalization necessary, very sick active supportive treatment necessary.
		C	10	Moribund. Fatal processes progressing rapidly.
			0	Dead.

General functional impairment

The Karnofsky Index (described earlier) was used to measure the level of physical functioning among patients in the study at the time of data collection. The index was completed by dialysis and transplant center staff. No attempt was made to have the staff report premorbid patient functional impairment. Most recently, the Karnofsky Index was used by Gutman and his associates (1981) in a study of patients on maintenance dialysis. Unfortunately, Gutman and his associates made no attempt to relate the Karnofsky Index scores to the treatment modality their patients were on.

In the present study, Karnofsky Index scores have been related to treatment modality. As shown in Table 11-2, transplant patients experience much less functional impairment than patients on the other three treatment modalities. Fully 79.1 percent of the transplant patients fall into the first two categories on the Karnofsky Index, indicating few or no symptoms of their disease. In-center hemodialysis and CPD patients are clearly the worst off, and home hemodialysis patients function quite well with 59.1 percent of them falling into the first two categories on the Karnofsky Index.

Specific functional limitations

As discussed earlier, respondents were asked a series of questions regarding the extent to which they are currently limited in various activities or have specific functional limitations because of their health. A summary of these responses for all patients by treatment modality is contained in Tables 11-3 and 11-4. In addition, respondents who indicated that they are currently limited in a particular physical activity were asked if they were limited in this way before they got kidney disease. These results are also presented in Table 11-3.

As these tables clearly show, there is considerable variation in current functional limitations among end stage renal disease (ESRD) patients by type of activity and treatment modality. Among all dialysis and transplant patients, more than 50 percent reported that they are limited in the kind of vigorous activities (i.e., running, lifting heavy objects, or participating in strenuous sports) they can do; have trouble walking several blocks or climbing a few flights of stairs; have trouble bending, lifting, or stooping; are unable to do certain kinds or amounts of work, housework, or schoolwork; are kept from working at a job, doing work around the house, or going to school; and are limited in any way from doing anything they want to do. Of course, as shown in Table 11-3 there are substantial variations across modalities. Among all patients, fewer than 20 percent need assistance travelling around the community; must stay indoors most or all of the day; must stay in bed or a chair most or all of the day; need help in walking (such as assistance by another person or by a cane, crutches, walker, artificial limbs, or braces); and need help eating, dressing, bathing, or using the toilet. With respect to the functional limitations shown in Table 11-4, of all ESRD patients, most had trouble lifting or carrying heavy weights. Approximately 20 percent reported that they were limited in their ability to reach or use fingers to grasp or handle, and 29 percent have problems using their eyes for reading or the inspection of things.

As seen from the data in Table 11-3, only a small

Table 11-2

Percent distribution of patients with end stage renal disease, by treatment modality and functional impairment (Karnofsky Index)

	Treatment modality				
Karnofsky Index category	All modalities	Home hemodialysis	In-center hemodialysis	CPD	Transplant
	Percent distribution				
1. Normal, no complaints, no evidence of disease	15.7	12.8	8.4	2.5	47.8
2. Able to carry on normal activity	39.7	46.3	36.3	45.0	31.3
3. Normal activity with effort	22.6	25.3	25.2	25.0	9.0
4. Care for self; unable to carry on normal activity	9.9	8.9	12.3	12.5	4.5
5. Requires occasional assistance but is able to care for most of his needs	5.6	3.6	7.5	8.8.	3.7
6. Requires considerable assistance	3.3	1.4	4.5	3.7	3.7
7. Disabled; requires special care and assistance	3.0	1.8	6.0	2.5	0.0
8. Severely disabled; hospitalization is indicated	0.0	0.0	0.0	0.0	0.0
9. Very sick, hospitalization necessary	0.0	0.0	0.0	0.0	0.0
10. Moribund	0.0	0.0	0.0	0.0	0.0

NOTES: Chi-square is 160.87, p-value is .0000. CPD is continuous peritoneal dialysis.

Table 11-3

Percent of respondents currently limited in specific activities because of their health and those limited before they got kidney disease, by treatment modality and activity limitation

Activity limitation	All modalities		Home hemodialysis		In-center hemodialysis		CPD		Transplant	
	Currently limited	Before kidney disease	Currently limited	Before kidney disease	Currently limited	Before kidney disease	Currently limited	Before kidney disease	Currently limited	Before kidney disease
	Percent									
A. Need assistance traveling around community	[1]18.4	2.6	11.9	2.4	25.2	3.2	30.9	1.2	7.7	2.1
B. Must stay indoors most or all of the day	[1]15.9	1.2	14.4	1.1	19.1	1.7	19.8	0.0	9.0	1.4
C. Must stay in bed or a chair most or all of the day	[1]16.0	1.4	14.0	0.7	19.7	2.3	19.8	0.0	9.0	1.4
D. Limited in types of vigorous activity can do	[1]83.6	19.6	88.4	23.2	84.7	19.1	92.6	23.5	66.7	11.8
E. Trouble walking several blocks or climbing few flights of stairs	[1]63.5	9.0	62.8	7.4	70.0	12.0	80.2	16.0	39.9	4.2
F. Trouble bending, lifting, or stooping	[1]53.5	7.9	49.0	6.3	57.3	10.8	80.2	8.6	38.2	3.5
G. Trouble walking one block or climbing one flight of stairs	[1]36.2	4.6	31.9	3.2	42.6	5.8	58.0	8.6	17.4	3.5
H. Needs assistance walking	[1]15.5	2.9	10.8	2.1	21.4	5.2	20.0	1.2	8.3	0.7
I. Unable to do certain kinds or amounts of work	[1]62.7	7.8	65.9	7.3	67.7	9.3	72.5	7.5	38.9	5.6
J. Unable to work at a job, do housework, or go to school	[1]54.8	5.6	50.2	3.9	65.7	7.8	69.6	7.6	29.9	3.5
K. Needs help eating, dressing, bathing, etc.	[1]6.8	.7	4.2	0.3	9.0	1.4	14.8	0.0	2.1	0.0
L. Limited in doing anything	[1]77.7	11.3	81.9	12.2	81.2	11.3	85.2	9.9	56.9	10.4

[1] Chi-square significant at .05 level when all modalities are compared at current time.

NOTE: CPD is continuous peritoneal dialysis.

Table 11-4

Percent of respondents with various functional limitations, by treatment modality and limitation

Limitation	Treatment modality				
	All modalities	Home hemodialysis	In-center hemodialysis	CPD	Transplant
			Percent		
A. Reaching	20.8	15.4	29.3	24.7	9.0
B. Using fingers to grasp or handle	21.4	16.1	31.3	19.8	9.0
C. Using eyes for inspection	29.2	18.9	38.0	24.7	31.0
D. Using eyes for reading	29.0	20.0	35.7	28.8	31.3
E. Lifting or carrying 10 pounds	33.3	28.7	42.0	46.2	14.6
F. Lifting or carrying 25 pounds	57.4	53.0	62.9	73.7	34.5
G. Lifting or carrying 50 pounds	76.5	71.3	79.3	91.1	59.6

NOTE: CPD is continuous peritoneal dialysis.

percent of dialysis and transplant patients were limited in their activities before they got their kidney disease. With the exception of being limited in the types of vigorous activities that patients could do and being limited in any way from doing what they wanted to do, less than 10 percent of all ESRD patients reported that they were limited in their activities because of their health prior to the onset of their disease.

When one examines the level of functional impairment across the four treatment modalities, some striking differences appear. As can be seen in Table 11-3, transplant recipients consistently report the lowest level of functional impairment among patients in the four modality groups. In addition, home hemodialysis patients, in general, are limited to a lesser extent than the average across all patient groups. CPD and in-center hemodialysis patients typically report the highest levels of functional impairment, consistently above the average for all modalities. The results presented in Table 11-4 confirm these general observations. With the exception of more vision problems among the transplant group (probably a result of the long-term use of steroids), patients with functioning grafts have the lowest levels of functional impairment and in-center hemodialysis and CPD patients have the highest levels of functional impairment. In the case of all variables, the differences in functional limitations across the four modalities are statistically significant at the .05 level.

When one examines differences in the extent of functional limitations among patients prior to their kidney disease, one observes much less variation across treatment modalities. In general, transplant patients report low levels of functional impairment, consistently lower than the average across all treatment modalities. These differences across the four modality groups, however, are not statistically significant.

Discussion

Results presented here clearly show that end stage renal disease (ESRD) patients, regardless of their current treatment modality, were less impaired prior to the onset of kidney disease than at the present time. Before the onset of kidney disease, patients on different treatment modalities did not differ in their level of functional impairment; however, at the present time treatment modality does appear to be associated with current level of functional impairment. Both transplant patients and home hemodialysis patients are less debilitated than in-center hemodialysis patients and CPD patients. These findings are consistent whether one looks at general functional limitations, as measured by the Karnofsky Index, or specific functional impairments, as measured by standard measures designed for this purpose.

Interpreting these results is complex and should be done with caution. First, as noted, patient case-mix rather than treatment modality could possibly account for much of the difference in functional limitations across patients. This is unlikely, however. Second, a unique dialysis or transplant center effect may be operating, such that patients at certain dialysis and transplant centers with an extreme emphasis on rehabilitation may be doing better than patients at other centers where rehabilitation is not a goal of primary importance. This too is unlikely. Third, it is possible, although again unlikely, that given data collection training procedures patients in responding to the survey questions may have confused the time periods to which the before and after questions referred. As noted above, for some patients, the time period prior to when they "got kidney disease" and the time period when they began ESRD treatment may be indistinguishable. Patients, therefore, may have been somewhat confused in answering the questions. Fourth, because some patients have been on more than one treatment modality since they began treatment for ESRD, the treatment modality effect that appears to exist may be somewhat contaminated. Finally, the length of time patients have been on their current treatment modality varies considerably across patients. In general, CPD patients have been on their modality for a much shorter period of time than patients on the other modalities.

Once again, these results, as results presented in previous chapters, underscore the need for a true longitudinal study of patients on all forms of treatment for ESRD (Evans et al., 1982b; 1982c, 1982d; 1982e; Garrison et al., 1983; Manninen et al., 1983). Elsewhere Evans and associates (1981) have noted that in the treatment of end stage renal disease, several critical and distinctly different time periods can be identified, as follows: the time prior to the onset of kidney disease, the time kidney disease is recognized as a clinical entity, the time at which treatment for kidney disease is initiated, and the time following the initiation of treatment. Disability will obviously vary according to the point in time at which the data are collected. Rarely are data collected during periods 1 and 2, and most researchers fail to recognize the critical differences between periods 3 and 4. Period 3 is a relatively unstable period and occurs whenever a patient is placed on therapy or makes a change in therapy. Period 4, perhaps, is the period of greatest interest because this period supposedly represents the time of long-term adjustment. Ultimately a longitudinal study design better enables one to collect data throughout the disease trajectory and to make less tentative and questionable statements concerning cause and effect. Whereas cross-section studies may reveal important associations, longitudinal studies do much to enhance the determination of causation.

In conclusion, the results reported here may also serve to direct greater attention to the rehabilitation of ESRD patients. Three years ago the National ESRD Patient Rehabilitation Task Force (1982) concluded that the full rehabilitation potential of ESRD patients is not being met. For example, results presented here would suggest that ESRD patients could potentially benefit from physical therapy. Apparently the rehabilitation needs of ESRD patients are not being met. Greater attention must be devoted to these needs if the overall status of ESRD patients is to be improved.

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Appendix 11-A.

Functional limitation questions adapted from the Rand Health Insurance Study

129. Some people with health problems find that they can do as much as they want to, while others may have to change their activities. When you travel around your community, does someone have to assist you because of your health?

YES 01

NO 02

(SKIP TO Q. 131)

130. Did you need assistance before you got kidney disease?

YES 01

NO 02

131. Do you have to stay indoors most or all of the day because of your health?

YES 01

NO 02

(SKIP TO Q. 133)

132. Did you have to stay indoors most or all of the day before you got kidney disease?

YES 01

NO 02

133. Are you in bed or a chair for most or all of the day because of your health?

YES	01
NO	02

(SKIP TO Q. 135)

134. Were you in bed or a chair for most or all of the day before you got kidney disease?

YES	01
NO	02

135. Does your health limit the kind of vigorous activities you can do, such as running, lifting heavy objects, or participating in strenuous sports?

YES	01
NO	02

(SKIP TO Q. 137)

136. Did your health limit the kind of vigorous activities you did before you got kidney disease?

YES	01
NO	02

137. Did you have any trouble either walking **SEVERAL BLOCKS** or climbing a **FEW FLIGHTS** of stairs, because of your health?

YES	01
NO	02

(SKIP TO Q. 139)

138. Did you have trouble walking several blocks or climbing a few flights of stairs before you got kidney disease?

YES	01
NO	02

139. Do you have trouble bending, lifting, or stooping because of your health?

YES	01
NO	02

(SKIP TO Q. 141)

140. Did you have trouble bending, lifting, or stooping before you got kidney disease?

YES 01

NO 02

141. Do you have any trouble either walking **ONE BLOCK** or climbing **ONE FLIGHT** of stairs because of your health?

YES 01

NO 02

(SKIP TO Q. 143)

142. Did you have trouble walking one block or climbing one flight of stairs before you got kidney disease?

YES 01

NO 02

143. Do you need help in walking such as assistance by another person or by a cane, crutches, walker, artificial limbs, or braces?

YES 01

NO 02

(SKIP TO Q. 145)

144. Did you need assistance in walking before you got kidney disease?

YES 01

NO 02

145. Are you unable to do certain kinds or amounts of work, housework, or schoolwork because of your health?

YES 01

NO 02

(SKIP TO Q. 147)

146. Were you unable to do certain kinds or amounts of work, housework, or schoolwork before you got kidney disease?

YES 01

NO 02

147. Does your health keep you from working at a job, doing work around the house, or going to school?

YES 01

NO 02

(SKIP TO Q. 149)

148. Did your health keep you from working at a job, doing work around the house, or going to school before you got kidney disease?

YES 01

NO 02

149. Do you need help with eating, dressing, bathing, or using the toilet because of your health?

YES 01

NO 02

(SKIP TO Q. 151)

150. Did you need help with eating, dressing, bathing or using the toilet before you got kidney disease?

YES 01

NO 02

152. Does your health limit you in any way from doing anything you want to do?

YES 01

NO 02

(SKIP TO Q. 154)

Appendix 11-B. Functional limitations questions from the 1978 Survey of Disability and Work

151. Does your health limit your ability to . . .

	YES	NO
A. REACH?	01	02
B. USE FINGERS TO GRASP OR HANDLE?	01	02
C. USE YOUR EYES FOR INSPECTION OF THINGS?	01	02
D. USE YOUR EYES FOR READING?	01	02
E. LIFT OR CARRY WEIGHTS UP TO 10 POUNDS?	01	02
F. LIFT OR CARRY WEIGHTS UP TO 25 POUNDS?	01	02
G. LIFT OR CARRY WEIGHTS UP TO 50 POUNDS?	01	02

Chapter 12. Health status by Sickness Impact Profile

Introduction

The quality of life of end stage renal disease (ESRD) patients on different treatment modalities has been described in previous chapters. In Chapter 11 results were presented concerning the functional abilities of patients according to treatment modality. In this Chapter attention will focus on a slightly different, although related, subject—health status. As in previous chapters, the purpose of this analysis is to examine differences in health status according to treatment modality. This is accomplished through the application of a multidimensional, standardized index referred to as the Sickness Impact Profile (SIP). The SIP measures a subject's perception of sickness-related behavioral dysfunction. It consists of 136 statements that are grouped into 12 categories, each describing an area of activity in which dysfunctional behavior may occur. Those statements to which a subject subscribes provide scores expressed as a percent of a total possible score. The SIP was developed at the University of Washington, and it has been applied to the study of patients undergoing treatment for a variety of conditions (Pollard et al., 1976; Bergner et al., 1976a; 1981; 1984; Evans et al., 1984).

Consistent with previous chapters in this report, it is acknowledged that health status may be a function of, or influenced by, factors other than treatment modality. Those patient characteristics such as age, sex, race, education, and duration of ESRD are here termed case mix. Both patient case-mix and dialysis and transplant center characteristics (i.e., center effects) may affect patient health status. In this chapter, emphasis is placed on analyzing case-mix factors, and individual center effects are not directly addressed. Exploratory analyses suggest that center effects and the combined effects of center and modality are not of great importance to these results.

In addition, however, a more complicated problem concerns the process by which patients are, for the lack of a better term, ''allocated'' to treatment modalities and the resultant relationships to outcomes such as health status. It can be argued that treatment modality allocation is partly a function of health status rather than health status being solely a function of treatment modality. In other words, patients may be placed on certain modalities because they are sicker (or healthier) than other patients. For example, in-center patients are generally thought to be sicker than home hemodialysis patients. As a result, differences in health status outcomes measured at various points in time subsequent to treatment may simply reflect their pretreatment health status. Similarly, transplant patients may have better health status outcomes because they were ''healthier'' patients to begin with. In short, there is much justification for attempting to control for patient case-mix differences. This, of course, has been accomplished and described in previous chapters where it has been shown that intermodality quality of life differences persist despite case-mix differences. This same approach to data analysis will be followed here.

Patients

All patients included in the National Kidney Dialysis and Kidney Transplantation Study were eligible for this analysis. This included 287 home hemodialysis patients, 347 in-center hemodialysis patients, 81 continuous peritoneal dialysis (CPD) patients, and 144 transplant patients. Complete sociodemographic and clinical characteristics of the patient sample have been provided in Chapter 5. The sample design and survey methodology have been described in Chapter 3. Given the focus of this chapter, additional commentary on the patient sample is warranted. As noted in Chapter 3, some patients were excluded from the initial sample frame because they were extremely sick, senile, emotionally unstable, or for other reasons that would have made it difficult or impossible for them to participate in a lengthy interview. The obvious inference is that such exclusions may bias the results of this study. Because this chapter is devoted to an analysis of health status, we felt it appropriate to assess the extent to which such a bias may be present.

It is estimated that nearly 11 percent of the patients at the participating dialysis and transplant centers were not approached concerning participation in the study because they would have been unable to be interviewed. Just over one-half of these exclusions were for medical reasons, although it was often difficult to differentiate the patients excluded for medical reasons from those excluded for social reasons. Ultimately, of every 100 persons approached to participate in the study, 12 refused. In addition, for every 100 patients contacted, another 12 were not contacted because of socioemotional and medical reasons. Approximately 10 percent of the patients who refused to participate felt that they were too sick to do so. Also, of the 859 patients interviewed, 12 refused to allow their medical records to be abstracted.

Although the implications of patient selection and nonresponse are analyzed in detail in Appendix 12-A, the conclusions reached therein are noteworthy here. The results indicate that even though both patient allocation factors and nonresponse may have influenced health status (i.e., Sickness Impact Profile scores), it is highly unlikely that the conclusions reached here concerning intermodality differences in functional status would change. In fact, it is possible that these differences would be exacerbated. Although it is important to keep in mind that those patients who were excluded from this study would have had SIP scores reflecting poorer health status than most patients in the study, the results of the sensitivity analysis presented in Appendix 12-A clearly indicated the exclusion of such patients should not change the results of intermodality comparisons.

Variables

Patient case mix

End stage renal disease (ESRD) modality patients can be distinguished according to their case-mix. As shown in Chapter 5 and summarized in Table 12-1, the modality case-mix of patients in this study differs according to age, sex, race, and education. Because these diferences may be critical to health status, the analyses must take them into account. Other variables included in the more complex analyses presented here include length of time with ESRD, presence of diabetes as the cause of renal failure, length of time on current treatment modality, experience with a failed kidney transplant (i.e., last transplant failed), and the presence of 10 comorbid conditions. These variables are also expected to relate to health status as measured by the Sickness Impact Profile.

Health status

As noted earlier, the Sickness Impact Profile was incorporated into the survey instrument as a measure of health status. The Sickness Impact Profile (SIP) is a standardized instrument consisting of 136 statements that measure sickness-related dysfunction along many dimensions. The 136 statements have been scaled and weighted; and they are divided into 12 categories, each of which describes an area of behavioral dysfunction (Table 12-2). Individual scores are computed for each of the categories and for a physical dimension, psychosocial dimension, and total SIP. The physical dimension is created by combining the body care and movement, mobility, and ambulation categories, and the psychosocial dimension is created by combining the emotional behavior, social interaction, alertness behavior, and communication categories. The total SIP score results from combining the weighted scores from all 12 categories. SIP scores represent the percent of the total possible scaled scores subscribed to by respondents for categories, dimensions, or overall. The higher the score, the more patients perceive themselves as being functionally limited.

During its extensive developmental period, the SIP has been shown to be both reliable and valid (Bergner et al., 1976a; 1976b; Pollard et al., 1976; Pollard, Bobbitt, and Bergner, 1978; Gilson et al., 1979). Through this developmental process and testing, the SIP has proved to have good test-retest reliability and to be valid as measured by good correspondence to other health status measures. In addition, the SIP was shown to be reliable for respondents who differed in both type and severity of dysfunction, with reliability not affected by different interviewers. Thus, the SIP provides a widely applicable measure of perceived sickness-related dysfunction, and it is sufficiently sensitive to contrast differences in health status among groups of subjects.

Appendix 12-B contains a brief and general examination of the validity and sensitivity of the SIP. Because data derived from the National Kidney Dialysis and Kidney Transplantation Study also provided many other measures of patient health status, these data were examined relative to their associations with the SIP. The

Table 12-1

Number, mean age, and years of school completed of patients with end stage renal disease, by treatment modality; and number and percent distribution of these patients by sex, race, and treatment modality

Item	Home hemodialysis	In-center hemodialysis	CPD	Transplant
Total sample	287	347	81	144
Age:				
Number of cases	287	345	81	144
Mean	47.0	51.9	49.8	37.2
Sex:				
Number of cases	287	346	81	144
		Percent distribution		
Male	64.1	50.0	45.7	56.3
Female	35.9	50.0	54.3	43.8
Race:				
Number of cases	287	346	81	144
		Percent distribution		
Black	8.7	42.5	9.9	11.8
White	86.4	53.5	84.0	87.4
Other	4.9	4.0	6.2	4.8
Years of school completed:				
Number of cases	286	341	81	143
Mean	12.8	11.5	11.9	12.2

NOTES: CPD is continuous peritoneal dialysis. Column percents may not add to 100 percent because of rounding error. Frequencies are slightly different than those of previous chapters. These changes are the result of matching Medicare reimbursement and utilization system data to these survey data and making appropriate adjustments.

Table 12-2

Categories and sample items from the Sickness Impact Profile

Category	Items describing behavior related to—	Selected items
SR	Sleep and rest	I sit during much of the day. I sleep or nap during the day.
E	Eating	I am eating no food at all, nutrition is taken through tubes or intraveneous fluids.
W	Work	I am not working at all. I often act irritable toward my work associates.
HM	Home managment	I am not doing any of the maintenance or repair work around the house that I usually do. I am not doing heavy work around the house.
RP	Recreation and pastimes	I am going out for entertainment less. I am not doing any of my usual physical recreation or activities.
A	Ambulation	I walk shorter distances or stop to rest often. I do not walk at all.
M	Mobility	I stay within one room. I stay away from home only for brief periods of time.
BCM	Body care and movement	I do not bathe myself at all, but am bathed by someone else. I am very clumsy in body movements.
SI	Social interaction	I am doing fewer social activities with groups of people. I isolate myelf as much as I can from the rest of the family.
AB	Alertness behavior	I have difficulty reasoning and solving problems, for example, making plans, making decisions, learning new things. I sometimes behave as if I were confused or disoriented in place or time, for example, where I am, who is around, directions, what day it is.
EB	Emotional behavior	I laugh or cry suddenly. I act irritable and impatient with myself, for example, talk badly about myself, swear at myself, blame myself for things that happen.
C	Communication	I am having trouble writing or typing. I do not speak clearly when I am under stress.

SOURCE: Gilson et al., 1979.

findings reported in Appendix 12-B clearly support previous claims concerning the validity of the SIP. In fact, the SIP seems capable of detecting small differences in functional status between and within the various ESRD treatment modality groups.

A problem frequently encountered when using various measures of health status is the interpretation of the scale scores. Making such scores meaningful is by no means straightforward. For example, two groups of subjects may have significantly different scores, but the question is whether these differences are meaningful. Fortunately, the SIP has been administered to a variety of types of patients (Bergner et al., 1984; McCusker and Stoddard, 1984; Evans et al., 1984) and, as a result, the scores can be compared from one patient group to another to assist with their interpretation. Also, as shown in Appendix 12-B, it is possible to relate SIP scores with other measures of functional status to establish validity. Finally, the results of a survey of a stratified random sample of members of a prepaid group practice provides a rough approximation of what the general population would score on the SIP (Bergner et al., 1981).

In principle, total SIP scores may range from 0 to 100, where a high score indicates poor health status, and a low score indicates good health. As the level of dysfunction experienced by the subject rises, so does the SIP score. In practice, the total mean score on the SIP ranges from 2 or 3 for a near typical control sample of the population (Bergner et al., 1981) to 35 or 37 for a homebound terminally ill or chronically ill sample (McCusker and Stoddard, 1984). Although the range of scores from 2 to 37 does not come close to the theoretically possible 100 percent, many different patterns of statements can be subscribed to and make it possible to compare patient groups across different diagnoses and types of dysfunction. In Appendix 12-B, which specifically deals with the validity of the SIP, there are several tables that facilitate the interpretation of what differences in SIP scores mean in terms of patient functional ability.

Statistical methods

A variety of statistical procedures were used to analyze these data. Among these was the t-test, which enables one to test the difference between means (averages) from two independent samples. In addition, the Pearson product moment correlation coefficient and its associated significance test were used to measure the strength of associations between SIP scores and selected patient characteristics within treatment modalities. A word of caution is warranted concerning the interpretation of these correlation coefficients across modalities. They measure the strength of the association (i.e., the tendency of higher or lower SIP scores to correspond with differences in patient characteristics), and they do not necessarily reflect the magnitude of the association (i.e., how drastic a SIP change is in relation to a change in patient characteristics). It is also noteworthy that correlation coefficients are affected by the level of measurement of the variables that are correlated. Correlations involving nominal or ordinal scale variables are typically depressed.

In addition, adjustments for patient case-mix differences have been accomplished using standard linear regression analysis. Thus, the possible independent effects of treatment modality on patient functional status (i.e., SIP scores) can be evaluated after patient case-mix factors are statistically held constant. Throughout the text of this Chapter, detailed comments on the use of these methods are presented at strategic points in the analysis. Because statistical significance is influenced by the number of cases available for analysis, there are many occasions in which practical or clinical significance must be judged apart from statistical significance (Feinstein, 1977; Ingelfinger et al., 1983).

Results

The results of this analysis are organized according to the following three major topics: observed unadjusted health status, age-sex-race adjusted health status, and case-mix adjusted health status. The analyses become progressively more sophisticated to take into account a variety of factors hypothesized to be related to functional impairment.

Observed unadjusted health status

An examination of Table 12-3 reveals that there are substantial differences in the health status of patients on various end stage renal disease (ESRD) treatment modalities. This is true for Sickness Impact Profile (SIP) categories, subscales (i.e., dimensions), and total scores. Transplant patients clearly experience the lowest level of functional impairment, and patients on continuous peritoneal dialysis (CPD) and in-center patients are most impaired. These latter two patient groups are similar, but divide about evenly on which has higher or lower scores on the various SIP categories. The largest absolute difference is on the work category, where CPD patients appear to fare poorest. The largest proportional differences are for the communication, eating, and alertness behavior categories, where in-center patients are more dysfunctional. In-center patients have a lower mean score on the physical dimension of the SIP than CPD patients do, but they have a higher psychosocial mean score.

Home hemodialysis patients take on an intermediate status between the transplant and in-center extremes. With only one exception, the home hemodialysis group scores are higher than those for the transplant group and lower than those for the in-center and CPD groups. That exception is for the eating category, where home patients averaged 8.0 and CPD patients averaged 6.3. (This is expected as CPD patients have fewer dietary restrictions.)

Unfortunately, mean scores can be misleading. They can, for example, mask bimodal or other distributions of scores. More detailed descriptive statistics for all patient groups for the SIP total score as well as for the physical and psychosocial dimensions are given in Table 12-4. As shown, the distributions of scores for each modality are well-behaved. They are all positively skewed, with the patient groups with higher means having heavier tails. It is also evident that modality medians have the same in-

Table 12-3

Mean Sickness Impact Profile scores for patients with end stage renal disease, by treatment modality patient group and Sickness Impact Profile category

SIP category	Home hemodialysis	In-center hemodialysis	CPD	Transplant
Number of cases	286	338	81	144
		Mean score		
Total SIP	9.5	13.9	13.7	5.5
Sleep and rest	15.5	21.7	21.6	6.3
Emotional behavior	7.9	8.5	10.4	5.0
Body care and movement	4.6	7.7	9.6	2.4
Home managment	14.7	24.0	23.3	7.5
Mobility	4.9	10.4	9.0	2.7
Social interaction	7.7	11.4	9.4	4.4
Ambulation	10.8	16.3	17.4	6.2
Alertness behavior	6.4	11.2	8.5	5.0
Communication	2.4	5.7	3.0	1.4
Work	37.7	45.0	51.0	28.4
Recreation and pastimes	18.2	23.7	24.0	9.0
Eating	8.0	10.2	6.3	3.1
Physical dimension[1]	6.1	10.3	11.3	3.3
Psychosocial dimension[2]	6.4	9.7	8.2	4.1

[1] Consists of weighted scores from body care and movement, mobility, and ambulation categories.

[2] Consists of weighted scores from emotional behavior, social interaction, alertness behavior, and communication categories.

NOTES: SIP = Sickness Impact Profile. CPD = continuous peritoneal dialysis.

termodality relationships, although their absolute values are lower than for the comparable means.

It is noteworthy that the percent of patients that had true zero scores (i.e., sickness has no impact upon perceived functional ability) also follows the pattern of the means and medians as well as the patterns demonstrated in other chapters of this report (Chapters 5, 6, 7, 11, 13). For the total SIP, 21.5 percent of the transplant patients, 5.2 percent of the home patients, and 2.7 percent of the in-center hemodialysis patients had zero scores. No CPD patients had a score of zero. Even though very sick patients were excluded from this study because of their inability to be interviewed, it is clear that some very sick patients were interviewed. An examination of Table 12-4 reveals many patients had relatively high SIP scores in the twenties, thirties, and higher.

It is generally acknowledged that the first year of ESRD treatment is a difficult year for most patients. A great deal of adjustment is required of them. For this reason, a separate analysis was undertaken of patients who had been on their present treatment modality for a year or more. It can be seen from Table 12-5 that the differences among ESRD patients already noted generally persist after the first year of treatment (Table 12-5). SIP scores for all patients are compared with those for patients who had been on their current modality for 1 year or more in Table 12-6. Limiting the analysis to patients who had been on their current modality for a year or more produced a lower mean total SIP score for the CPD patient group but a higher mean total score for the home hemodialysis patient group. No change in mean total scores occurred for the in-center hemodialysis or the transplant patient groups. Many of the differences in mean scores for the SIP categories and dimensions became less pronounced between the CPD and home patient groups. Caution should be exercised in interpreting these findings relevant to CPD because the number of cases in that group dropped to only 37.

In Table 12-7, the results of t-tests for the differences of means between all possible pairs of treatment modality groups are presented. Only in-center and CPD patients do not differ significantly from each other in terms of total SIP scores. In fact, within various SIP subcategories in-center hemodialysis and CPD patients differ only with regard to communication and eating. For all other SIP categories and dimensions, there appears little difference between in-center and CPD patients. In contrast, almost all other pairwise comparisons among modalities are statistically significant. The SIP categories where minimal differences occur include emotional behavior, communication, and alertness behavior. In addition, and somewhat related, is the general finding that sharper differences occur on the physical dimension than on the psychosocial dimension of the SIP.

Once again, an attempt has been made to take length of time on current treatment modality into account. The results of this analysis of patients on their current modality 1 year or more are presented in Table 12-8. Clearly the impact is not substantial, although the differences and their significance levels are smaller. Computation of the t-tests on logarithmic transformations of the SIP scores to compensate for their skewness had no appreciable impact on these findings. This was expected because of the large number of cases and well-behaved distributions.

Age-sex-race adjusted health status

In order to determine if the differences in SIP scores result from differences in the age, sex, and race composition of the modality patient groups, a crude age, sex, and race standardization was performed. This procedure consisted of adjusting the mean scores for each modality so as to obviate the effect of differences in the age, sex, and race structure of the modalities. Because there is no standard age, sex, and race template that is most appropriate for the comparisons, each modality was standardized to the demographic structure of the other modalities to which it was compared. Thus, the total SIP score was adjusted for each group to reflect the same age, sex, and race composition of the group with which it was compared. For example, if modality A's mean SIP score was being standardized to the age, sex, and race distribution of modality B, the mean SIP score for each specific age, sex, and race subgroup of modality A's patients would first be computed. Then a new overall (adjusted) mean SIP score would be created by weighting the modality A age, sex, and race subgroup means by the distribution of modality B's patients across those subgroups and computing a new weighted overall mean.

These adjustments were accomplished by using six age categories (18-24 years, 25-34 years, 35-44 years, 45-54 years, 55-65 years, and 65 years of age or over), two sex categories, and three race categories (black, white, and other). When a cell for the modality being standardized was empty, the mean score for the next largest category was substituted (in race, sex, and age order). Thus, if a specific age, sex, and race cell was empty, the overall sex mean score for that age group was substituted. Although there are much more elaborate methods of imputing scores than the procedure used here, this crude method was sufficient for the present purposes with the provision that adjustments would only be presented where a low proportion of the weighted cells were imputed. In addition, the age, sex, and race adjustments were limited only to those patients who had been on their current modality for 1 year or longer.

In the tables that follow, only adjusted scores that required less than 10 percent of their weighted scores to be imputed are tabled. Those with 10 percent or more are excluded because the given modality has a much more limited age and/or race distribution than the modality to which it is being standardized (i.e., fewer older patients and/or fewer patients who were not white). It has been possible to calculate adjusted scores for transplant patients by restricting the comparison to particular age groups. These comparisons are explained in notes recorded on each table.

Table 12-4

Percent distribution of patients with end stage renal disease, by treatment modality, physical and psychosocial dimensions, and total SIP scores

	Total				Physical dimension				Psychosocial dimension			
SIP score	Home hemodialysis	In-center hemodialysis	CPD	Transplant	Home hemodialysis	In-center hemodialysis	CPD	Transplant	Home hemodialysis	In-center hemodialysis	CPD	Transplant
Number of cases	286	338	81	144	286	338	81	144	286	338	81	144
						Percent distribution						
Total[1]	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
0-4	38.1	22.5	17.3	61.8	65.7	47.0	38.3	77.1	62.9	49.4	46.9	77.1
5-9	25.2	22.2	23.5	20.1	14.0	18.3	18.5	11.8	16.8	16.9	23.5	11.8
10-14	17.1	18.6	23.5	8.3	8.4	9.5	18.5	4.2	8.7	10.9	11.1	3.5
15-19	7.7	12.7	13.6	4.2	4.2	10.1	9.9	2.1	3.1	6.8	9.9	0.0
20-24	5.6	9.5	11.1	2.1	1.7	3.0	2.5	2.8	3.1	5.3	1.2	3.5
25-29	2.1	5.3	4.9	2.8	1.7	3.6	6.2	2.1	2.1	4.1	4.9	2.1
30-34	2.4	2.7	0.0	0.0	1.7	2.1	0.0	0.0	1.4	1.5	0.0	0.7
35-39	1.0	2.1	3.7	0.7	0.7	2.4	1.2	0.0	1.0	1.8	1.2	0.0
40-44	0.0	2.7	2.5	0.0	0.7	1.5	2.5	0.0	0.3	1.2	0.0	1.4
45-49	0.0	0.9	0.0	0.0	0.3	0.6	0.0	0.0	0.0	0.6	0.0	0.0
50 and over	0.7	0.9	0.0	0.0	0.7	2.1	2.5	0.0	0.3	1.5	1.2	0.0
Zeros only	5.2	2.7	0.0	21.5	35.0	18.3	13.6	61.8	23.8	20.4	19.8	52.1
Mean score	9.5	13.9	13.7	5.5	6.1	10.3	11.3	3.3	6.4	9.7	8.2	4.1
Standard error	.54	.61	1.08	.59	.58	.67	1.36	.52	.51	.64	1.05	.65
Median score	6.8	11.8	12.1	3.4	2.4	5.5	5.4	0.0	3.4	5.1	5.4	0.0

[1] Some of the columns do not add to 100.0 because of rounding error.

NOTES: SIP = Sickness Impact Profile. CPD = continuous peritoneal dialysis.

Table 12-5

Mean total SIP scores for patients with end stage renal disease, by treatment modality patient group, SIP categories, and physical and psychosocial dimensions

SIP category and dimension	Home hemodialysis	In-center hemodialysis	CPD	Transplant
Number of cases	227	271	37	116
		Mean score		
Total SIP scores	10.0	13.9	12.2	5.5
	(.64)	(.68)	(1.44)	(.64)
Sleep and rest	16.4	22.0	22.2	6.8
Emotional behavior	8.0	8.6	10.3	5.5
Body care and movement	5.2	7.7	8.0	2.4
Home management	15.6	23.7	18.6	7.1
Mobility	5.5	10.5	7.5	2.5
Social interaction	7.5	11.4	6.7	4.4
Ambulation	11.9	16.0	13.9	6.2
Alertness behavior	6.8	11.8	6.4	5.2
Communication	2.7	5.7	2.8	1.5
Work	39.1	44.9	54.1	26.7
Recreation and pastimes	19.0	24.0	22.4	9.5
Eating	8.1	10.2	6.0	2.7
Physical dimension	6.9	10.3	9.3	3.3
	(.70)	(.74)	(1.57)	(.57)
Psychosocial dimension	6.5	9.8	6.5	4.2
	(.59)	(.72)	(1.28)	(.64)

NOTES: Patients on current modality 1 year or longer. CPD = continuous peritoneal dialysis. SIP = Sickness Impact Profile. Standard errors are in parentheses.

Table 12-6

Comparison of mean SIP scores for all patients with those for patients on their current modality for 1 year or more, by treatment modality and physical and psychosocial dimensions

	Treatment modality			
Dimension	Home hemodialysis	In-center hemodialysis	CPD	Transplant
		SIP score		
All patients				
Total	9.5	13.9	13.7	5.5
Physical	6.1	10.3	11.3	3.3
Psychosocial	6.4	9.7	8.2	4.1
Patients on current modality 1 year or more				
Total	10.0	13.9	12.2	5.5
Physical	6.9	10.3	9.3	3.3
Psychosocial	6.5	9.8	6.5	4.2

NOTES: SIP = Sickness Impact Profile. CPD = continuous peritoneal dialysis.

Table 12-7

T-test values and significance levels for SIP treatment modality patient group comparisons, by comparison group, SIP categories, and physical and psychosocial dimensions

SIP category and dimension	Modality patient group comparison					
	Home with in-center	Home with CPD	Home with transplant	In-center with CPD	In-center with transplant	CPD with transplant
Total	***−5.3	***−3.5	***5.0	***0.2	***9.9	***6.7
Sleep and rest	***−3.6	*−2.1	***6.0	0.0	***9.5	***5.4
Emotional behavior	−0.5	−1.2	*2.2	−0.9	**2.7	*2.5
Body care and movement	***−3.5	***−3.4	*3.1	−1.3	***6.7	***5.1
Home management	***−5.7	***−3.4	***4.6	0.3	***9.5	***6.1
Mobility	***−4.9	**−2.7	*2.5	0.9	***7.1	***4.2
Social interaction	***−4.0	−1.4	***3.3	1.5	***6.6	***3.7
Ambulation	***−4.9	**−3.1	***3.8	−0.5	***8.2	***5.1
Alertness behavior	***−3.7	−1.1	1.1	1.3	***4.1	+1.7
Communication	***−4.5	−0.7	1.6	**2.8	***5.9	+1.8
Work	**−2.8	***−3.4	*2.7	−1.5	***5.0	***5.1
Recreation and pastimes	***−3.3	*−2.1	***5.2	−0.1	***8.2	***5.4
Eating	***−4.0	*2.2	***9.3	***4.9	***13.7	***4.0
Physical dimension	***−4.7	***−3.5	***3.6	−0.7	***8.3	***5.5
Psychosocial dimension	***−4.0	−1.5	**2.8	1.2	***6.1	***3.3

NOTES: T-test utilizing separate variance estimates (i.e., the modality population variances are not assumed to be equal). CPD is continuous peritoneal dialysis. SIP is Sickness Impact Profile. Significance levels are as follows:

+ p ≤ .100
* p ≤ .050
** p ≤ .010
*** p ≤ .001

Table 12-8

T-test values and significance levels for SIP treatment modality patient group comparisons, by comparison group, SIP categories, and physical and psychosocial dimensions

SIP category and dimension	Modality patient group comparison					
	Home with in-center	Home with CPD	Home with transplant	In-center with CPD	In-center with transplant	CPD with transplant
Total	***−4.2	−1.4	***5.0	1.1	***9.0	***4.3
Sleep and rest	**−2.9	−1.3	***5.3	−0.1	***8.0	**3.3
Emotional behavior	−0.4	+−0.7	+1.7	−0.5	*2.1	1.5
Body care and movement	*−2.5	−1.5	***3.4	−0.2	***6.1	**3.2
Home management	***−4.4	−1.0	***5.0	1.6	***8.9	***3.6
Mobility	***−3.8	−1.0	**3.0	1.4	***6.7	*2.5
Social interaction	***−3.7	0.6	**3.0	**3.1	***6.0	1.5
Ambulation	***−3.2	−0.8	***4.1	0.9	***7.2	**3.1
Alertness behavior	***−3.3	0.2	1.1	*2.5	***3.9	0.6
Communication	***−3.5	−0.0	+1.7	*2.2	***5.2	1.0
Work	*−2.0	**−2.9	***3.3	+−1.8	***4.9	***4.8
Recreation and pastimes	**−2.6	−0.9	***4.6	0.4	***7.0	**3.3
Eating	***−3.4	+1.7	***9.2	***3.5	***13.1	**2.9
Physical dimension	***−3.3	−1.4	***4.0	0.6	***7.5	***3.6
Psychosocial dimension	***−3.5	−0.0	*2.5	*2.2	***5.5	1.6

NOTES: Data are for patients on current modality 1 year or longer. T-test utilizing separate variance estimates (i.e., the modality population variances are not assumed to be equal). SIP is Sickness Impact Profile. CPD is continuous peritoneal dialysis. Significance levels are as follows:

+ p ≤ .100
* p ≤ .050
** p ≤ .010
*** p ≤ .001

Table 12-9

Unadjusted and age-, sex-, and race-adjusted total SIP mean scores for patients with end stage renal disease, by treatment modality patient groups

		Age-, sex-, and race-adjusted scores			
Patient groups	Unadjusted mean scores	Home hemodialysis	In-center hemodialysis	CPD	Transplant
		Adjusted mean score			
Home hemodialysis	10.0 (227)	10.0	11.1	11.0	9.0
In-center hemodialysis	13.9 (271)	12.3	13.9	13.1	10.2
CPD	12.2 (37)	N/A	N/A	12.2	N/A
Transplant	5.5 (116)	[1]N/A	[2]N/A	[3]N/A	5.5

[1] If the adjustments are limited to the age groups under 55 years of age, the mean score for home hemodialysis patients is 8.7 and the adjusted mean score for transplant patients is 4.5 (only 2.7 percent of the weighted scores are imputed).

[2] If the adjustments are limited to the age groups under 55 years of age, the mean score for in-center hemodialysis patients is 12.1 and the adjusted score for transplant patients is 8.7 (only 5.6 percent of the weighted scores are imputed).

[3] If the adjustments are limited to the age groups under 65 years of age, the mean score for CPD patients is 12.1 and the adjusted mean score for transplant patients is 5.5 (8.1 percent of the weighted scores are imputed).

NOTES: N/A = Not appropriate because too many cells for the adjusted group are empty and would have to be imputed.
SIP is Sickness Impact Profile.
CPD is continuous peritoneal dialysis.
Numbers in parentheses are numbers of end stage renal disease patients.
Data are for patients on current treatment modality 1 year or more.

An examination of Table 12-9 reveals that the mean scores for the modalities remain in the same relative order when adjusted for age, sex, and race, but the differences between them decrease. When in-center hemodialysis patient scores are age, sex, and race adjusted to the home hemodialysis patient base, instead of a 3.9 difference in scores (13.9 compared with 10.0), the difference is reduced to 2.3 (12.3 compared with 10.0). When the home hemodialysis patient score is adjusted to the in-center demographic distribution, the difference is reduced although not as much.

Adjusting home and in-center hemodialysis mean scores to the transplantation modality age, sex, and race base substantially reduces their mean scores, but the relative order of the modalities remain unchanged. When similar adjustments are made for both the physical and psychosocial dimensions of the SIP, as depicted in Tables 12-10 and 12-11, the conclusions that can be drawn are much the same as those drawn about the total SIP score age, sex, and race adjustments.

Based on these analyses, it is reasonable to conclude that some of the differences among patients on various treatment modalities can be explained by age, sex, and race, but differences in health status among modalities persist, and the relative ordering of modalities changes little. Of the three variables examined here, age appears to be the most important.

To conclude this discussion of the relationship between patient demographics and health status, perhaps a few comments are in order concerning the experience of patients whose last kidney transplant failed and who were on one of the three dialysis modalities. These patients were compared with patients with functioning grafts using the separate variance estimate form of the t-test for patients who had been on their current modality for a year or more.The failed graft group had significantly higher scores on both the SIP physical dimension (6.2 versus 3.3, $t = 2.45$, $p = .016$) and the total SIP score (9.8 versus 5.5, $t = 3.94$, $p = .000$). On the psychosocial dimension, the mean for the failed graft group was higher than that for the transplant group, but was not significant at the .05 level (6.2 versus 4.2, $t = 1.79$, $p = .075$). Within their current modality groups, the failed graft patients generally had similar, though slightly lower, scores than their current modality peers. Thus, the last failed graft group had a perceived functional status worse off than the current transplantation group but roughly equivalent to their current modality group counterparts.

Case-mix adjusted health status

Health status is a complex outcome that represents the interplay among many factors including the patients' social milieu and various personal characteristics, as well as a variety of structural factors. It is impossible within the course of any analysis to properly take into account all possible factors that may affect health status. The analyses which follow are intended to determine to what extent health status, as reflected by the Sickness Impact Profile (SIP), may be determined by factors other than treatment modality. To do this, multiple regression analysis is used.

In these analyses, health status is statistically modeled as a function of current treatment modality, age, sex, race, education, years with end stage renal disease (ESRD), diabetic renal disease, last experience with a failed transplant, comorbidity (i.e., health conditions in addition to ESRD defined more stringently than in other chapters), and length of time on current treatment modality. Although comorbidity may dictate the treatment modalities for which a patient is suitable, it is also evident that many ESRD patients develop significant comorbidity subsequent to treatment and sometimes as a result of treatment. In a study such as this where data have been collected cross-sectionally, it is difficult to

Table 12-10

Unadjusted and age-, sex-, and race-adjusted physical dimension SIP mean scores for patients with end stage renal disease, by treatment modality patient groups

		Age-, sex-, and race-adjusted scores			
Patient groups	Unadjusted mean scores	Home hemodialysis	In-center hemodialysis	CPD	Transplant
			Adjusted mean score		
Home hemodialysis	6.9 (227)	6.9	8.4	8.0	5.9
In-center hemodialysis	10.3 (271)	10.2	10.3	9.4	6.3
CPD	9.3 (37)	N/A	N/A	9.3	N/A
Transplant	3.3 (116)	[1]N/A	[2]N/A	[3]N/A	3.3

[1] If the adjustments are limited to the age groups under 55 years of age, the mean score for home hemodialysis patients is 6.0 and the adjusted mean score for transplant patients is 3.6 (only 2.7 percent of the weighted scores are imputed).
[2] If the adjustments are limited to the age groups under 55 years of age, the mean score for in-center hemodialysis patients is 7.5 and the adjusted score for transplant patients is 5.2 (only 5.6 percent of the weighted scores are imputed).
[3] If the adjustments are limited to the age groups under 65 years of age, the mean score for CPD patients is 8.9 and the adjusted mean score for transplant patients is 3.6 (8.1 percent of the weighted scores are imputed).
NOTES: N/A = Not appropriate because too many cells for the adjusted group are empty and would have to be imputed.
SIP is Sickness Impact Profile.
CPD is continuous peritoneal dialysis.
Numbers in parentheses are numbers of end stage renal disease patients.
Data are for patients on current treatment modality 1 year or more.

Table 12-11

Unadjusted and age-, sex-, and race-adjusted psychosocial dimension SIP mean scores for patients with end stage renal disease, by treatment modality patient groups

		Age-, sex-, and race-adjusted scores			
Patient groups	Unadjusted mean scores	Home hemodialysis	In-center hemodialysis	CPD	Transplant
			Adjusted mean score		
Home hemodialysis	6.5 (227)	6.5	6.5	6.9	5.8
In-center hemodialysis	9.8 (271)	8.6	9.8	9.0	7.4
CPD	6.5 (37)	N/A	N/A	6.5	N/A
Transplant	4.2 (116)	[1]N/A	[2]N/A	[3]N/A	4.2

[1] If the adjustments are limited to the age groups under 55 years of age, the mean score for home hemodialysis patients is 5.7 and the adjusted mean score for transplant patients is 4.0 (only 2.7 percent of the weighted scores are imputed).
[2] If the adjustments are limited to the age groups under 55 years of age, the mean score for in-center hemodialysis patients is 9.1 and the adjusted score for transplant patients is 5.3 (only 5.6 percent of the weighted scores are imputed).
[3] If the adjustments are limited to the age groups under 65 years of age, the mean score for CPD patients is 6.8 and the adjusted mean score for transplant patients is 4.1 (8.1 percent of the weighted scores are imputed).
NOTES: N/A = Not appropriate because too many cells for the adjusted group are empty and would have to be imputed.
SIP is Sickness Impact Profile.
CPD is continuous peritoneal dialysis.
Numbers in parentheses are numbers of end stage renal disease patients.
Data are for patients on current treatment modality 1 year or more.

determine at what point in time patients develop comorbidity or the cause of the comorbidity and to what extent this comorbidity precluded the assignment of patients to certain modalities. During the first year on the various treatment modalities, the effects of surgery, training, and adjustment are important and influence the SIP's measurement of dysfunction. Analysis of patients on their current modalities for less than 1 year clearly showed the length of time on a modality was often as important as which modality they were on. Thus, this regression analysis is limited to those patients who have been on their current modality for a year or longer. These patients have had the time necessary to stabilize on their modalities.

For those patients who had been on their current treatment modality 1 year or more, three regression models each have been estimated for three separate dependent variables. These variables include the total SIP score, the physical SIP score, and the psychosocial SIP score. The first model, called the ''modality model,'' simply estimates the effect of treatment modality on each of the three dependent variables. The second model, referred to as the ''selected-model,'' simultaneously estimates the effects of several selected independent variables, in addition to treatment modality. The third model, referred to as the ''full-model,'' simultaneously estimates the effects of all the independent variables, including modality, which were felt to be the most important influences on health status. The idea here is to determine if unique treatment modality effects persist after other variables thought to be critical to health status have been taken into account. Statistical significance in this discussion is considered a significance level of .050 or less, and a significance level of from .100 to .050 is described as marginally significant.

The correlation and regression analysis results for the total SIP score are presented in Table 12-12. As shown, nearly all the independent variables are significantly correlated with total SIP score. The magnitude of some of the associations is weak. The highest correlations with the total SIP are for in-center hemodialysis, transplantation, age, education, diabetes, length of time with transplant, and specific comorbid conditions. The correlation between in-center hemodialysis and the total SIP is positive, indicating that in-center patients are generally more dysfunctional. Similarly, older patients are more dysfunctional, patients who are more educated are less dysfunctional, diabetics are more functionally limited, and patients with most of the comorbid conditions are more dysfunctional. The results also indicate that the longer patients have had their transplants, the healthier they are and, conversely, the longer they have been on in-center hemodialysis the more they perceive themselves to be functionally limited.

The three regression models displayed in Table 12-12 provide information on the magnitude of the associations. The modality model shows the relationship of treatment modality to total SIP score. As shown, in-center hemodialysis patient have higher SIP scores than patients on all other modalities. However, only home hemodialysis and transplant patients differ significantly from in-center hemodialysis patients. CPD patients do not differ significantly. In addition, a separate test for the difference between the unstandardized home and transplant regression coefficients showed they were significantly different.

The full model in Table 12-12 is more complicated and reveals that when the additional control variables are included in the model, the difference between in-center hemodialysis patients and home hemodialysis patients is no longer significant. The difference between transplant patients and home patients also was not significant. Only transplant patients have a significantly lower total SIP score than in-center patients, but the effect is reduced substantially. Also, as was apparent from the correlation coefficients, higher educated patients had lower SIP scores, diabetics had higher scores, and patients with various comorbidities had higher scores. In particular, patients with angina, other cardiovascular problems, respiratory disease, gastrointestinal problems, musculoskeletal disorders, and neurological disorders all had higher scores on the SIP. The adjusted R square for this more complicated multiple regression model reveals that about 27 percent of the variation in total SIP scores is explained by the variables included in the model. The joint F-test to determine whether the modality dummy variables contributed significantly as a group in explaining SIP scores was not significant.

The selected model in Table 12-12 represents an attempt to better specify the model. Only those comorbidities that are felt unlikely to be caused by modality treatment are included (i.e., angina, myocardial infarction; other cardiovascular problems; respiratory disease, and neurological problems and cerebrovascular accidents). Other variables that were found to be unimportant in the full model were also excluded. As can be seen from Table 12-12, the results for this more contrained model are similar to those for the full model, but they make clearer the relative independent importance of the various factors. Clearly education and diabetic renal condition have the strongest independent associations with SIP scores of any of the variables.

The same analysis procedures described above were applied to the analysis of the physical dimension of the SIP, as well as the psychosocial dimension. As shown in Table 12-13, the results for the physical dimension are similar to those for the total SIP, although the treatment modality effect is clearly weaker. Moreover, the independent effects of diabetic renal failure and neurological disorders on the physicial dimension of the SIP scores are particularly noteworthy. Age and respiratory problems were also important but to a lesser degree. The adjusted R square, or percent of variance explained by the full model, for the physicial SIP is 30 percent, slightly higher than for the total SIP score.

Finally, the psychosocial dimension of the SIP was subjected to separate analysis. As shown in Table 12-14, the results are similar to those for the physical dimension of the SIP. Although the percent of variance explained in the psychosocial SIP score regression is reduced considerably to about 12 percent in the full model, what is interesting is that transplantation is the only treatment modality that has a nearly significant independent effect on psychosocial SIP scores. Other variables that had significant independent relationships with psychosocial SIP scores were education, diabetic renal failure, and respiratory disease. Nonetheless, far fewer variables are significantly related to the psychosocial dimension SIP score model than are related to the total and physical dimension SIP score models.

Several special regression analyses were performed to test the robustness of the regression results. Regression analyses were performed that excluded all total SIP scores of 30 or higher, that limited the analysis to patients whose onset of ESRD was after the age of 23 (to negate ESRD's possible influence on education), that used logarithmic transformations of the SIP scores, and that limited cases to different combinations of modalities. In all these analyses, the results were remarkably consistent and similar to those presented earlier.

Clearly, these multivariate analyses reveal that many of the large unadjusted intermodality differences in health status as measured by the SIP may be a function of case-mix variations. This finding holds true not only for total SIP scores, but for SIP scores for both the physical and psychosocial dimensions. In fact, unlike other analyses of quality of life that revealed that unique treatment modality effects persisted even after case-mix variables were taken into account, the present analysis suggests that, with respect to health status, treatment modality effects are minimized when case-mix variables

Table 12-12

Total SIP regressions for ESRD treatment modality patient groups, by selected variables

Independent variables (dummy variables unless otherwise noted)	Simple Pearson correlation coefficient	Unstandardized regression coefficients (F statistic): Treatment Modality only (Modality model)	Treatment modality with selected controls (Selected model)	Treatment modality with all controls (Full model)
Modality				
In-center hemodialysis	***.248	—	—	—
Home hemodialysis	+–.070	***–4.04 (19.90)	–1.09 (1.64)	–.787 (.28)
Continuous peritoneal dialysis	.027	–1.95 (1.26)	–.486 (.10)	–.944 (.05)
Transplantation	***–.249	***–8.62 (59.10)	***–4.50 (16.90)	*–4.35 (4.72)
Age in decimal years	***.292	—	*.0562 (3.91)	+.0555 (3.30)
Sex				
Female	*.090	—	—	—
Male	*–.090	—	+–1.26 (3.01)	–1.15 (2.42)
Race				
White	**–.118	—	—	—
Black	*.100	—	—	.0300 (.00)
Other	**.054	—	—	1.72 (.75)
School years completed (complete years)	***–.253	—	***–.600 (27.14)	***–.572 (22.60)
Years with ESRD (complete years)	***–.143	—	—	–.0790 (.21)
Diabetic renal condition	***.204	—	***6.61 (26.49)	***6.08 (21.05)
Time on current modality				
In-center (complete months)	***.180	—	—	.00330 (.02)
Home (complete months)	+–.076	—	—	–.000142 (.00)
CPD (complete months)	.026	—	—	.0362 (.03)
Transplantation (complete months)	***–.211	—	—	.00850 (.11)
Last transplant failure	–.046	—	—	.187 (.02)
Comorbid conditions				
Angina, myocardial infarction	***.235	—	*2.70 (5.90)	*2.62 (5.22)
Other cardiovascular problem	***.296	—	***3.32 (10.59)	**2.77 (7.10)
Respiratory disease	***.250	—	***5.54 (15.45)	***5.51 (13.41)
Neurological problems and cerebrovascular accidents (e.g., stroke)	***.241	—	***4.99 (12.57)	**4.60 (9.47)
Gastrointestinal problems	***.229	—	—	*2.54 (4.15)
Musculoskeletal disorders (e.g., bone disease)	***.226	—	—	*2.58 (6.44)
Infection other than access problems or peritonitis	**.127	—	—	.737 (.10)
Hepatitis	.043	—	—	–3.28 (.83)
Hematologic problems other than anemia	.038	—	—	–3.95 (2.13)
Spinal abnormality (lower back, arthritis)	**.128	—	—	–1.47 (.64)
Constant	—	***14.13 (530.54)	***15.2 (51.25)	***14.5 (32.61)
Adjusted R-square	—	***.087 (20.87)	***.268 (21.90)	***.270 (10.27)
Joint F-test on modality	—	—	***(5.78)	(1.61) not significant

NOTES: ESRD is end stage renal disease. CPD is continuous peritoneal dialysis. SIP is Sickness Impact Profile.

Significance levels are as follows:

+ $p \leqslant .100$
* $p \leqslant .050$
** $p \leqslant .010$
*** $p \leqslant .001$

Data are for 628 patients on current treatment modality 1 year or more.
Total SIP mean is 11.08.

Table 12-13

Physical dimension SIP regressions for ESRD treatment modality patient groups, by selected variables

Independent variables (dummy variables unless otherwise noted)	Simple Pearson correlation coefficient	Unstandardized regression coefficients (F statistic): Treatment Modality only (Modality model)	Treatment modality with selected controls (Selected model)	Treatment modality with all controls (Full model)
Modality				
In-center hemodialysis	***.198	—	—	—
Home hemodialysis	†–.069	***3.61 (13.62)	–.300 (.11)	–.757 (.24)
Continuous peritoneal dialysis	.032	–1.17 (.39)	.502 (.09)	–.443 (.01)
Transplantation	***–.190	***–7.09 (34.29)	†–1.92 (2.83)	–3.11 (2.25)
Age in decimal years	***.322	—	*.112 (14.20)	***.113 (12.67)
Sex				
Female	*.102	—	—	—
Male	*–.102	—	*–1.93 (6.40)	*–1.74 (5.21)
Race				
White	–.057	—	—	—
Black	.043	—	—	–.627 (.41)
Other	.039	—	—	1.07 (.27)
School years completed (complete years)	***–.190	—	***–.397 (10.83)	***–.414 (11.07)
Years with ESRD (complete years)	*–.082	—	—	.171 (.90)
Diabetic renal condition	***.252	—	***8.65 (41.42)	***8.38 (37.36)
Time on current modality				
In-center (complete months)	***.144	—	—	–.0155 (.44)
Home (complete months)	–.064	—	—	–.0110 (.29)
CPD (complete months)	.036	—	—	.00783 (.00)
Transplantation (complete months)	***–.151	—	—	.00543 (.04)
Last transplant failure	–.058	—	—	.462 (.14)
Comorbid conditions				
Angina, myocardial infarction	***.235	—	*2.87 (6.08)	*2.76 (5.40)
Other cardiovascular problem	***.293	—	**2.94 (7.59)	*2.33 (4.70)
Respiratory disease	***.255	—	***6.03 (16.73)	***6.22 (15.92)
Neurological problems and cerebrovascular accidents (e.g., stroke)	***.306	—	***8.20 (30.99)	***7.86 (25.69)
Gastrointestinal problems	***.231	—	—	*2.68 (4.30)
Musculoskeletal disorders (e.g., bone disease)	***.260	—	—	**3.34 (10.03)
Infection other than access problems or peritonitis	***.140	—	—	1.28 (.28)
Hepatitis	.024	—	—	–5.55 (2.23)
Hematologic problems other than anemia	.015	—	—	*–6.21 (4.93)
Spinal abnormality (lower back, arthritis)	***.137	—	—	–1.60 (.71)
Constant	—	***10.48 (250.77)	**6.04 (7.43)	*5.64 (4.63)
Adjusted R-square	—	***.052 (12.56)	.286 (23.80)	***.302 (11.83)
Joint F-test on modality	—	—	(1.11) not significant	(.75) not significant

NOTES: ESRD is end stage renal disease. CPD is continuous peritoneal dialysis. SIP is Sickness Impact Profile.

Significance levels are as follows:
† p ≤ .100
* p ≤ .050
** p ≤ .010
*** p ≤ .001
Data are for 628 patients on current treatment modality 1 year or more.
Total SIP mean is 7.90.

Table 12-14

Psychosocial dimension SIP regressions for ESRD treatment modality patient groups, by selected variables

Independent variables (dummy variables unless otherwise noted)	Simple Pearson correlation coefficient	Unstandardized regression coefficients (F statistic)		
		Treatment Modality only (Modality model)	Treatment modality with selected controls (Selected model)	Treatment modality with all controls (Full model)
Modality				
In-center hemodialysis	***.202	—	—	—
Home hemodialysis	+–.073	***–3.49 (14.37)	–1.51 (2.64)	.252 (.02)
Continuous peritoneal dialysis	–.026	–3.52 (3.97)	–2.57 (2.29)	–3.91 (.77)
Transplantation	***–.155	***–5.90 (26.81)	**–3.78 (10.16)	+–3.84 (3.09)
Age in decimal years	***.140	—	–.0161 (.27)	–.0261 (.61)
Sex				
Female	*.080	—	—	—
Male	*–.080	—	–1.11 (1.98)	–.904 (1.27)
Race				
White	*–.093	—	—	—
Black	+.068	—	—	–.505 (.24)
Other	+.069	—	—	2.26 (1.09)
School years completed (complete years)	***–.200	—	***–.508 (16.54)	***–.503 (14.70)
Years with ESRD (complete years)	*–.100	—	—	–.0350 (.03)
Diabetic renal condition	***.153	—	***5.27 (14.29)	***4.84 (11.26)
Time on current modality				
In-center (complete months)	***.158	—	—	–.0198 (.65)
Home (complete months)	*–.082	—	—	–.00721 (.11)
CPD (complete months)	–.018	—	—	.121 (.27)
Transplantation (complete months)	**–.126	—	—	.0122 (.19)
Last transplant failure	–.053	—	—	–1.13 (.75)
Comorbid conditions				
Angina, myocardial infarction	***.150	—	1.74 (2.07)	1.94 (2.41)
Other cardiovascular problem	***.191	—	*2.44 (4.85)	+2.09 (3.40)
Respiratory disease	***.193	—	***5.26 (11.83)	***5.67 (11.93)
Neurological problems and cerebrovascular accidents (e.g., stroke)	**.118	—	1.44 (.88)	1.42 (.75)
Gastrointestinal problems	***.159	—	—	2.23 (2.69)
Musculoskeletal disorders (e.g., bone disease)	**.114	—	—	1.04 (.88)
Infection other than access problems or peritonitis	.065	—	—	–.177 (.00)
Hepatitis	.016	—	—	–3.40 (.75)
Hematologic problems other than anemia	.026	—	—	–2.02 (.47)
Spinal abnormality (lower back, arthritis)	.041	—	—	–2.83 (2.00)
Constant	—	***10.05 (259.91)	***14.8 (41.27)	***14.5 (27.50)
Adjusted R-square	—	***.043 (10.43)	***.125 (9.15)	***.119 (4.40)
Joint F-test on modality	—	—	*(3.66)	(1.32) not significant

NOTES: ESRD is end stage renal disease. CPD is continuous peritoneal dialysis. SIP is Sickness Impact Profile.

Significance levels are as follows:
+ p ⩽ .100
* p ⩽ .050
** p ⩽ .010
*** p ⩽ .001

Data are for 628 patients on current treatment modality 1 year or more.
Total SIP mean is 7.58

are considered. To summarize, only the total SIP score difference between transplantation and in-center patient groups remained significant (though reduced in magnitude) following the introduction of control case-mix factors in the full model. The corresponding transplantation and home patient group difference was only marginally significant. In the case of the physical SIP dimension, only the transplantation and in-center patient group difference was even marginally significant. And finally, the transplantation and in-center group difference for the psychosocial SIP dimension was marginally significant as was the transplant/home patient group difference. In all cases, the transplant patient group had lower SIP scores than the other groups did. In addition, the following variables had the strongest independent associations with SIP scores after the influence of all other analysis variables were statistically controlled: patient age, diabetic renal condition, education, respiratory conditions, and neurological problems and cerebrovascular accident.

It must be emphasized that these regression findings do not preclude the possibility that modality effects may be stronger than indicated in the selected model and especially the full model. They do, however, indicate that it cannot be ruled out that the observed intermodality differences (with the exception of those related to transplantation) may be explainable on the basis of case-mix factors.

Discussion

Health status is an important outcome worthy of consideration in the analysis of alternative treatments for a given health condition. The Sickness Impact Profile (SIP) is a standardized measure of health status. As described above, the SIP was administered to patients undergoing various types of treatment for end stage renal disease (ESRD). The results showed that patients on various treatment modalities have significant and important differences in SIP scores, suggesting that health status outcomes for some patients are better than others. Bivariate analysis (health status unadjusted for patient case mix) showed that transplant patients had the highest overall health status (least dysfunction), followed by home hemodialysis patients, continuous peritoneal dialysis patients (CPD), and in-center hemodialysis patients. However, health status can be a function of variables other than treatment. It is known, for example, that the case mix of patients varies according to treatment modality. Thus, health status scores for all patients were adjusted for age, sex, and race. These adjustments revealed that differences, though reduced, continued to persist in the overall health status of patients on various treatment modalities. The ordering of treatment modalities from best to worst was as follows: transplantation, home hemodialysis, continuous peritoneal dialysis, and in-center hemodialysis. In short, age, sex, and race did not alter the overall pattern of relationships previously described for the unadjusted analyses. Finally, to better account for other case-mix determinants, multiple regression analysis was used to examine the effects of a wider array of case-mix variables. These analyses revealed that when years with ESRD, length of time on current treatment modality, last experience with a failed graft, diabetic renal condition, education, and comorbidity are considered in addition to age, sex, and race, unique treatment modality effects are eliminated with the exception of kidney transplantation. In other words, the only treatment modality that continues to exercise a significant unique effect on health status, independent of patient case mix, is transplantation relative to in-center hemodialysis. The difference between transplantation and home hemodialysis also remains marginally significant after the introduction of case-mix controls.

These results suggest that an ongoing assessment of the health status of ESRD patients is a worthy endeavor. Moreover, it would appear that a longitudinal study design has substantial benefits over a cross-sectional design. This is largely because health status is a state rather than a trait, and consequently, can be highly variable over time. Also, it is evident that health status can function as both an independent and dependent variable. On the one hand, as an independent variable, health status may dictate the treatment modalities for which a patient may be suitable. For example, patients in poor health are not good candidates for either transplantation or home hemodialysis and may only be marginally acceptable candidates for CPD. On the other hand, health status may reflect the outcome of treatment. For example, certain patients may benefit greatly from transplantation, deriving benefits over and above those offered by other treatment modalities. In this regard, health status is a dependent variable and treatment modality an independent or predictor variable. Cross-sectional study designs necessarily make it difficult to sort out these relationships. A longitudinal study design, however, permits more direct interpretation. This would allow observation of changing SIP scores through time as modality changes were made and also provide information on the chronology of the incidence of comorbid conditions. In addition, a longitudinal study could provide information on those patients who die. Note that this study has the weakness of only analyzing those patients who have survived. Such longitudinal data might also shed light on why higher levels of education are strongly associated with less perceived dysfunction. At present it can only be speculated that this association may be the result of more educated patients demonstrating better regimen compliance, demanding better care, having more financial resources, being treated better, and/or perceiving life differently. A longitudinal study design should be a consideration in future studies of patients undergoing various forms of treatment for end stage renal disease.

Finally, several comments regarding this chapter's results and those of Chapter 6 are appropriate. Previously, quality of life has been described as having two dimensions—one objective and the other subjective. The objective dimension was concerned with physical functioning and the subjective reflects socioemotional status. The Sickness Impact Profile (SIP) preserves this distinction with its physical and psychosocial dimensions, but it also offers a composite of the two in the form of a total

SIP score. The validity and sensitivity of the SIP as a measure of perceived behavioral dysfunction has been demonstrated by using various data collected in the National Kidney Dialysis and Kidney Transplantation Study that reflect constructs related to those that the SIP is designed to measure. That the findings of this chapter relative to the SIP do not wholly parallel those of the quality of life analysis (Chapter 6) should be understandable. In the earlier chapter, intermodality differences remained significant after control variables similar to those utilized in this chapter were employed. Since the SIP is designed to measure perceived health related behavioral dysfunction, it represents but a subset of the broader health status and quality of life realms. Of the quality of life variables discussed in Chapter 6, the Karnofsky Index comes closest to measuring a construct that the SIP attempts to measure via its physical dimension. The Karnofsky Index, as modified for this study, grossly measures the functional status of patients through one question addressed to a knowledgeable health professional. In contrast, the physical dimension of the SIP measures patient perceived health related physical behavioral dysfunction via 45 interview statements. That there are differences in what the various indexes are measuring is clear from an examination of Table 12B-6, in which correlation coefficients between the SIP and the quality of life variables presented in Chapter 6 by treatment modality group are shown. The coefficients range from a low of −.24 to a high of only −.61. It is, thus, understandable that analysis results can legitimately differ because variable constructs and measurements are different.

In conclusion, the SIP has been found to be a sensitive and valid measure of patient perceived health related behavioral dysfunction. This analysis has demonstrated that there are large differences in functional status as measured by the SIP between ESRD treatment modality patient groups. But those differences may be a function of the case mix of the modality patient groups except in the case of transplantation, which appears to have a unique impact on reducing perceived behavioral dysfunction.

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Appendix 12-A.
Impact of patient exclusion and patient nonresponse

The methodology and sample design of the National Kidney Dialysis and Kidney Transplantation Study, along with appropriate cautions, are briefly discussed above in this chapter and are elaborated upon more fully in Chapter 3. In addition, a comparison of survey respondents with the end stage renal disease population relative to demographic characteristics is provided in Chapter 4. The purpose of this appendix is to briefly evaluate the probable effects of patient exclusion and patient nonresponse on the analysis of health status.

Patient exclusion as it is used here denotes patients excluded from being interviewed because of serious social or emotional or medical problems. Such exclusions were generally made by a physician or other staff member at each dialysis and transplant center. Social and emotional problems included language problems, mental retardation, severe behavioral disorders, or other conditions that would lead one to question the ability of the patient to understand and provide meaningful responses to the interview. Medical problems included serious conditions that would make it impossible for the patient to complete a rather lengthy personal interview within the survey period. For other patients ill at the time of initial contact, repeated attempts were made to schedule an interview at a later date. Thus, this exclusion category was used only as a last resort after making every attempt to conduct an interview with these patients.

Patient nonresponse refers to those patients who were contacted for an interview but refused to participate. The overall response rate to this survey, as noted in Chapter 3, was approximately 90 percent.

It is important to evaluate the implications of patient exclusion and patient nonresponse because of their possible influence on any conclusions that can be drawn about the relative health status of the patients studied. Because patients excluded from the study for serious medical and social or behavioral problems would be expected to have high SIP scores, differences according to modality in such exclusions are clearly of interest. It is important to keep in mind that the patients examined in this study are those who were healthy enough to be approached for an interview. Thus, the results can be biased to the extent that excluded patients would change the observed response patterns. The implications of patient nonresponse are not as clear. Nonrespondents may not necessarily have higher or lower SIP scores than respondents. But any systematic bias by modality and SIP score for nonrespondents could have the same type of implications just noted for excluded patients.

The exit forms that were returned for patients were tabulated by therapy and reason for exit. As noted in Chapter 3, many of the reasons for patient exclusion were related to problems with the accuracy of the center's patient list and the time lag between the creation of the list, sampling, and actual interviewing (e.g., patient death, age under 18, and relocation). Other reasons were designed to assure that patients had stabilized on a treatment modality (e.g., currently in a home hemodialysis or CPD training program or a recent change in treatment modality type). Patients were also excluded from the study for administrative convenience (i.e., patient was not needed to complete center modality quota). Only three categories of exits are relevant to evaluating survey representativeness. As explained previously, patients excluded from the survey because of medical and social or emotional reasons are of interest as well as those who were approached for an interview but refused to participate. But there were other reasons for nonparticipation that were not included in the summary of the returned exit forms. Eighty-nine exit forms were not returned (presumably because many of the patients were not needed to meet center patient sample quotas), and other patients were excluded from participation in the study before the sample was drawn. A reexamination of the exit forms where social or emotional reasons were given for not participating indicates many of them could be more aptly classified as medical exclusions. In addition, evaluation of the exit forms of patients who refused to participate indicates many of these patients said they were too sick to participate in a long interview. All these facts have been taken into consideration in evaluating the effect patient exclusion and nonresponse have on this analysis.

To make estimates of patient exclusion and nonresponse rates, the following factors should be noted in addition to the summary of the exit forms for patients not interviewed (Chapter 3):

- Approximately 10 patients were excluded from 1 center's population list before the center's population list was sent for sampling. These patients were excluded for medical and social or emotional reasons.
- Several physicians at one center refused to let any of their patients participate. Forty patients were not included in the pool from which the center had its patients sampled.
- Ninety-six patients were excluded from the sample before it was drawn. These patients were excluded from the study on the lists sent for sampling.
- No exit forms were received for 89 patients who were not interviewed.
- Rereview of the 465 returned exit forms indicates that 7 of the 35 patients listed as being excluded for social or emotional reasons are better categorized as being excluded for medical reasons.
- Many of the patients who refused to be interviewed did so because they said they were too ill to be interviewed (10 of 101 refused to be interviewed exit forms).

- One home hemodialysis patient and nine in-center hemodialysis patients who were interviewed had unusable SIP scores because they were incomplete.

Table 12-A-1 is based on assumptions intended to estimate the highest reasonable impact of patient exclusion and nonresponse (especially for medical reasons). It was created by making the following assumptions:

- The 40 patients excluded because their doctors refused to let them participate were ignored (i.e., they were assumed to be like all the patients included).
- The 89 missing exit form patients were assumed to be distributed in the same way as the 465 patient exit forms described above.
- The 10 patients excluded before the patient list was prepared were assumed to be distributed in the same manner as the 96 actually listed and excluded. Only about one-third would have been included in the sample.
- The 96 patients excluded before the sample was drawn were evaluated as to reason for exclusion. Twenty-six were found to be excluded for medical reasons, and 52 were excluded for social or emotional reasons. Only about one-third of them would have been included in the sample.
- Ten percent of those who refused to be interviewed did so for medical reasons. This same percent was assumed to apply to the no exit form group.
- The incomplete SIP score patients are assumed to have scored the same as other patients on the same modality as they were on.

In all tables contained in this appendix, patients who originally were designated as not eligible for the study for social or emotional reasons and who were reevaluated as medical exits are reassigned to the medical reasons category. Refusal patients who indicated medical reasons for not participating are not reassigned because of the subjective nature of their decision and because they might have indicated being too ill as an excuse not to participate.

By using the above assumptions, the resultant estimated counts can be used to evaluate the largest reasonable impact patient exclusion and nonresponse could have on the results.

In Table 12-A-1, it can be seen that the percent of patients excluded from the survey for medical reasons was highest for CPD and in-center hemodialysis patients and lowest for transplant patients. The percents correspond, in rank order, to scores on the SIP. Nearly twice the percent of CPD and in-center hemodialysis patients were excluded as transplant patients. This is not surprising because patients on the three noncenter modalities (i.e., home hemodialysis, CPD, and transplantation), who became severely ill would most likely be placed on in-center hemodialysis.

Among patient treatment modality groups, in-center hemodialysis had the highest percent (7.6) of patients excluded for social or emotional reasons. The home and CPD groups were lowest with the transplant group in an intermediate position. Many of those excluded for social or emotional reasons were excluded because they were unable to take the interview in English. Others had few followup visits to the center scheduled (and lived out of the interview radius) and/or had home environments that were not satisfactory for the interviews (e.g., these ranged from a convicted felon to a particularly active prostitute).

The highest percent of patients who were approached to participate but refused was for the in-center group

Table 12-A-1

Percent distribution of patients excluded from study, by treatment modality and exclusion reasons

Exclusion reasons	Home hemodialysis	In-center hemodialysis	CPD	Transplant
	Percent distribution			
Total	100.0	100.0	100.0	100.0
Estimated patients excluded for medical reasons	4.9	6.9	7.2	3.8
Estimated patients excluded for social or emotional reasons	2.2	7.6	1.0	5.6
Estimated patients who refused to be interviewed	[1]12.1	[2]12.6	4.2	8.0
Estimated patients who were interviewed	80.9	73.0	87.6	82.6
Estimated response rate = respondents divided by the sum of respondents and estimated nonrespondents	87.0	85.3	95.4	91.2
Estimated overall response rate = 87.7				
Estimated sample size (X)	355	475	93	174
Actual number of respondents (N)	287	347	81	144

[1] Four of these patients (plus an estimated .8 of a patient) indicated they were too sick to be interviewed.

[2] Six of these patients (plus an estimated 1.1 patients) indicated they were too sick to be interviewed.

NOTES: CPD = continuous peritoneal dialysis. See text for explanation of how estimates were made. Columns may not add to 100.0 because of rounding error.

(12.6 percent), and the lowest was for the CPD group (4.2 percent). The percent of home hemodialysis nonrespondents (12.1 percent) corresponded most closely to the in-center group, and the percent of transplant nonrespondents was intermediate (8 percent). Some of the home and in-center patients indicated that they were too sick to participate. Examination of the exit forms filled out by the interviewers indicates that some of these patients were quite ill, and several attempts were made to interview them.

It is shown in Table 12-A-1 that those modalities with high SIP scores were also the groups with a high percent of patients excluded for medical reasons. With the exception of CPD, the same relationship held for patient refusals. Exclusions for social or emotional reasons are distributed differently but, as explained above, this category has more to do with non-ESRD related factors. To examine the possible impact of these findings, a simple sensitivity analysis was performed.

The sensitivity analysis results are tabulated in Table 12-A-2 for medical reasons only and in Table 12-A-3 for medical, social or emotional, and nonresponse reasons. Note that only one-half of the estimated nonrespondents were counted in the second table. It is believed that many of those who refused to participate did not do so for reasons connected with functional disability. Using one-half the number of nonrespondents in the sensitivity analysis represents both a cautious and conservative decision. Although many patients were also excluded for social or emotional reasons unrelated to functional status (e.g., poor proficiency in English), they were, nonetheless, included in the sensitivity analysis.

Two alternative assumptions can be made when performing the sensitivity analysis. The first is that all the patients who did not participate averaged the same SIP score regardless of treatment modality. If this assumption is made, it is clear from the results presented in Tables 12-A-2 and 12-A-3 that the nonparticipation of these patients did not substantively change the intermodality findings. This is true, even though the average scores of 20, 30, and 40 are very high average scores in comparison with actual empirical findings from other studies as described in the main text of this Chapter. A second possible assumption is that the patients who did not participate in the study had different mean SIP scores according to treatment modality. For instance, if the patients who did not participate for medical reasons

Table 12-A-2

Sensitivity of modality patient group total SIP scores to patient exclusion for medical reasons

				Adjusted mean total SIP scores if excluded patients averaged:		
Treatment modality	Unadjusted mean total SIP score (patients)	Number of interviewed patients	Estimated patients excluded for medical reasons (rounded)	20	30	40
Home hemodialysis	9.5	287	17	10.1	10.6	11.2
In-center hemodialysis	13.9	347	33	14.4	15.3	16.2
Continuous peritoneal dialysis	13.7	81	7	14.2	15.0	15.8
Transplant	5.5	144	7	6.2	6.6	7.1

NOTE: SIP is Sickness Impact Profile.

Table 12-A-3

Sensitivity of modality patient group total SIP scores to patient exclusions and nonresponse

				Adjusted mean total SIP scores if excluded patients averaged:		
Treatment modality	Unadjusted mean total SIP score (patients)	Number of interviewed patients	Estimated maximum number of patients excluded or not responding[1] (rounded)	20	30	40
Home hemodialysis	9.5	287	46	11.0	12.3	13.7
In-center hemodialysis	13.9	347	99	15.3	17.5	19.7
Continuous peritoneal dialysis	13.7	81	10	14.4	15.5	16.6
Transplant	5.5	144	23	7.5	8.9	10.3

[1] Only one-half the number of nonrespondents are utilized because many of them did not refuse because of medical or social or emotional problems (i.e., high SIP scores). All the social or emotional exclusion patients are counted, although some were excluded for reasons such as proficiency with the English language, and all those excluded for medical reasons are counted. Thus, the number of patients utilized to analyze the sensitivity of modality SIP scores to patient exclusion and nonresponse is almost certainly overestimated here or at least the probable maximum. If the other half of the nonrespondents were included in the adjusted scores with the mean of actual respondents, the adjusted scores would be slightly lower.

NOTE: SIP is Sickness Impact Profile.

(Table 12-A-2) averaged a SIP score of 20 for in-center patients but a score of 40 for home patients, the adjusted scores would be 14.4 for the in-center group and 11.2 for the home group. In other words, there could be a substantial difference in the scores of patients who were excluded from the analysis for medical reasons, but the difference between the two modalities would still persist.

Evaluation of Tables 12-A-2 and 12-A-3 indicates that it would take huge differences in nonparticipating patient SIP scores by modality to change the conclusions of this analysis. For instance, if nonparticipating home patients averaged SIP scores of 40 and nonparticipating in-center patients averaged the modality participating patient mean SIP score of 13.9, the adjusted scores would be 13.7 for home patients and 13.9 for the in-center patients (Table 12-A-3). But such a difference in nonparticipating patient scores is extremely unlikely. In fact, it is probably more correct to assume that mean SIP scores for nonparticipants would be higher for the modality groups with the highest patient SIP scores (i.e., in-center and CPD). In-center hemodialysis is often the treatment of last resort for seriously ill patients. Also, CPD may serve as a last resort for patients who have developed serious blood access problems. Other chapters in this report show that in-center hemodialysis respondents are more likely to be poor, unable to work, and have more comorbidity. In addition, they have more functional limitations and a lower sense of well-being. It does not seem likely that the nonparticipating in-center patients would be substantially better off than the participating patients. In fact, it is very doubtful that home hemodialysis patients could have scores high enough to change the results unless they were hospitalized and switched to in-center hemodialysis.

A score as high as 40 on the overall SIP is rare and indicates extreme dysfunction. For instance, McCusker and Stoddard (1984) administered the SIP to a group of 66 chronically and terminally ill homebound patients (e.g., cancer, stroke, and arthritis patients) and found that the 14 terminally ill patients had a mean total SIP score of 35.7 and that the 52 nonterminally ill patients had a mean score of 35.8 (McCusker, 1984). Those scores did not include the work category, but its inclusion for this group of patients who were mostly 65 years of age or over would not have increased scores by more than two points. Therefore, we conclude that it is highly unlikely that the inclusion of nonparticipants in the NKDKTS would have changed the substantive results of this analysis. In fact, their inclusion might have increased the observed intermodality differences. In future survey designs, it may be possible to reduce the effect of nonrespondents through the use of patient caretakers who could respond to the Sickness Impact Profile as patient surrogates (McCusker and Stoddard, 1984).

A final note is in order concerning the comparative health status of patients in the NKDKTS and those in other major studies of ESRD patients. Only one other study permits direct comparison on a common indicator of health status or functional ability. In an earlier study, Gutman, Robinson, and Stead (1981) used the Karnofsky Index to study the functional ability of patients on dialysis. Unfortunately, no distinction was made between patients on home hemodialysis or in-center hemodialysis in the study by Gutman, Robinson and Stead. Also, neither transplant patients nor CPD patients were included in their analysis. Despite these incompatibilities, it is possible to determine how well patients in the NKDKTS compare with those in the study by Gutman, Robinson, and Stead.

Table 12-A-4 shows the distribution of Karnofsky Index scores among the patients in the two studies. Clearly, as shown, the patients in the study by Gutman, Stead, and Robinson (1980) are somewhat sicker than those in the NKDKTS. However, when the percent distribution of in-center patients in the NKDKTS is adjusted to take nonresponse into account, we find the distributions are more similar. This adjustment simply adds nonresponding and unselected patients to the NKDKTS at the high end of the score to match the Gutman, Stead and Robinson distribution. The composition

Table 12-A-4

Percent distribution of hemodialysis patients in the NKDKTS and those in the Gutman, Stead, and Robinson Study, by Karnofsky categories

Karnofsky categories		Gutman, Stead, and Robinson study	NKDKTS		
			In-center hemodialysis patients only		Home hemodialysis patients only
Gutman[1]	NKDKTS[2]	All patients	Not adjusted for nonresponse	Adjusted for nonresponse	Not adjusted for nonresponse
Number of cases		2,480	323		280
Number of centers		18	11		11
			Percent distribution		
90-100	1-2	30.4	45.2	42.3	59.3
80-89	3	25.3	25.4	23.8	25.4
70-79	4	21.1	12.7	11.9	8.9
40-69	5-7	21.0	16.7	20.0	6.4
1-39	8-10	2.1	0.0	2.1	0.0

[1] Lower Karnofsky Index scores denote more functional limitation.

[2] For the NKDKTS, the Karnofsky Index was scored on a 10-level categorical scale, with higher categories indicating more functional limitation.

NOTE: NKDKTS = National Kidney Dialysis and Kidney Transplantation Study.

of patients in the two studies were similar with regards to age, race, and sex. The study by Gutman, Stead, and Robinson included 12.0 percent of patients who were diabetics, and the NKDKTS included 8.0 percent. There were, however, differences in the administration of the Karnofsky Index that may account for some differences in the distribution of patients in the two studies on the index categories.

Based on the foregoing, we conclude that the results of our analysis of the health status of ESRD patients on differing treatment modalities is not substantively affected by either patient exclusion or nonresponse. In addition, we conclude that even though patients in this study may be slightly healthier than patients in at least one other large scale investigation, we feel that the breadth of the analysis in the NKDKTS allowed by personal interviews greatly outweighs the bias that may be introduced in studies that rely solely on reports of the health status of patients by those persons who are responsible for their care.

Appendix 12-B.
Validity of the Sickness Impact Profile

Extensive studies have been conducted to demonstrate both the reliability and the validity of the Sickness Impact Profile (SIP). The SIP has been found to have the necessary properties that are expected of a psychometric index. Nonetheless, the purpose of this appendix is to use the extensive data obtained in the National Kidney Dialysis and Kidney Transplantation Study (NKDKTS) to assess the validity and sensitivity of the SIP. Patients participating in the NKDKTS were asked numerous questions related to their health status and overall quality of life. If the SIP is a valid measure, one would expect that it would relate to these measures in a predicatable manner. The tables and discussion that follow will, by and large, show that this is the case.

In Table 12-B-1, Sickness Impact Profile scores are related to primary disease diagnosis according to treatment modality. The idea here is not to look for significant differences across modalities but rather to determine if the overall pattern of relationships between SIP scores and diagnosis are as expected. Because diabetic renal failure is considered to be among the more severe of renal conditions, one would expect that patients with this diagnosis would have higher SIP scores than patients with other renal conditions. As shown in Table 12B-1, this is certainly true of dialysis patients of all types. Only among transplant patients is this not true. Among transplant recipients, the highest SIP score is found for patients with hypertensive renal disease. Also, among dialysis patients it is noteworthy that the SIP scores are in the predicted direction—in-center hemodialysis patients are the most dysfunctional, followed by CPD, and home hemodialysis patients.

In Table 12-B-2, SIP scores are related to the Karnofsky Index according to treatment modality. Although the number of cases is small at the extreme end of the Karnofsky Index, thus affectng the stability of the estimates, the results are generally in the predicted direction. The lower the Karnofsky score, the lower the SIP score. In general, subject to case availability, as the Karnofsky Index scores increase, so do the scores on the SIP. In most instances where the number of cases is sufficient, the modalities can again be hierarchically arranged from least dysfunctional to most dysfunctional as follows: transplant, home hemodialysis, continuous peritoneal dialysis (CPD), and in-center hemodialysis. It should be noted that where there are discontinuities between the SIP and Karnofsky scores the Karnofsky Index requires subjective evaluation of subtle patient differences by a health professional (e.g., between categories 4 and 5, and between categories 6 and 7). Because the Karnofsky Index is more limited in scope and is the result of a medical provider's evaluation, it is not surprising that there are some differences. Examination of the corresponding SIP physical dimension scores results in the same conclusions.

In Table 12-B-3, physical dimension SIP scores are related to the presence or absence of various comorbid conditions according to treatment modality. One would expect to find patients with comorbid conditions to have higher SIP scores than those who do not, to the extent their perceived functional status is limited. As shown in Table 12-B-3, in every instance where there is more than one case, this is true. In fact, some of the differences are dramatic. The presence of a comorbidity

Table 12-B-1

Mean total SIP scores for patients with end stage renal disease, by current treatment modality patient group and primary diagnosis of renal condition

Primary diagnosis of renal condition[1]	Number of cases	Home hemodialysis	Number of cases	In-center hemodialysis	Number of cases	CPD	Number of cases	Transplant
Total	279	9.5	328	14.1	80	13.6	140	5.5
Interstitial (including pylonephritis and obstruction)	33	9.2	24	15.7	12	17.2	20	6.5
Polycystic	42	8.7	27	11.1	8	12.1	7	1.6
Primary renal disease involving glomerular-arteriolar structures (including glomerulonephritis, and most "unknown")	125	8.6	119	12.7	24	10.8	73	4.6
Primary hypertensive renal disease	14	8.4	59	13.9	7	10.7	9	11.1
Nephroscleroses	8	12.3	32	15.5	5	9.0	6	5.0
Systemic lupus erythematosis	5	10.3	4	13.8	2	15.4	2	0.2
Diabetes	23	14.8	32	22.3	13	20.1	11	10.7
Myolema	0	—	3	21.8	0	—	0	—
Other	29	10.3	28	9.9	9	12.8	12	4.6

[1] Question from medical record abstraction form. Evaluation by staff at patient's center.

NOTES: SIP is Sickness Impact Profile. CPD is continuous peritoneal dialysis.

Table 12-B-2

Mean total SIP scores for patients with end stage renal disease who scored similarly on the Karnofsky Index, by current treatment modality patient group and Index category

Karnofsky Index category[1]	Number of cases	Home hemodialysis	Number of cases	In-center hemodialysis	Number of cases	CPD	Number of cases	Transplant
1. Normal, no complaints, no evidence of disease	36	4.7	27	7.8	2	3.4	64	2.8
2. Able to carry on normal activity, minor signs and symptoms of disease	130	7.0	119	10.3	36	11.1	42	5.7
3. Normal activity with effort, some signs and symptoms of disease	71	10.9	82	12.5	20	11.3	12	6.5
4. Care for self, unable to carry on normal activity or do active work	25	15.5	41	17.7	10	19.5	6	13.2
5. Requires occasional assistance but is able to care for most of his needs	9	14.8	22	21.4	7	19.3	5	13.8
6. Requires considerable assistance and frequent medical care	4	39.7	13	27.7	3	28.5	5	17.6
7. Disabled, requires special care and assistance	5	24.0	19	27.2	2	27.2	0	—

[1] Question from Medical Record Abstraction Form. Evaluation by staff at patient's center.

NOTES: The Karnofsky Index actually has three categories more severe than category 7, but none of the patients of this study were so evaluated. These three categories are: 8) severely disabled, hospitalization is indicated although death is not imminent; 9) very sick, hospitalization necessary; and 10) moribund, fatal process progressing rapidly. The patients from the study centers who would have fallen into these three groups were excluded from the analysis as explained earlier in the text. The Index was modified to utilize a 10-level ordinal scale in this study as opposed to the regular continuous 100-point scale. SIP is Sickness Impact Profile. CPD is continuous peritoneal dialysis.

Table 12-B-3

Mean physical dimension SIP scores for comorbid conditions, by current treatment modality patient group and comorbid condition

Comorbid condition (Does patient manifest at least a slight limitation of physical activity?)	Response	Number of cases	Home hemodialysis	Number of cases	In-center hemodialysis	Number of cases	CPD	Number of cases	Transplant
Angina, myocardial infarction	Yes	26	8.6	54	16.0	5	23.2	5	12.4
	No	198	6.5	213	8.9	32	7.1	107	2.9
Other cardiovascular problems	Yes	42	12.2	70	15.7	5	19.0	3	8.5
	No	182	5.5	197	8.4	32	7.8	109	3.2
Respiratory disease	Yes	10	16.9	35	18.7	2	10.4	1	0.0
	No	214	6.3	232	9.1	35	9.2	111	3.4
Neurological problems and cerebrovascular accident, including stroke	Yes	15	22.3	30	18.7	2	15.5	0	—
	No	209	5.7	237	9.3	35	9.0	112	3.4
Gastrointestinal problems	Yes	16	20.6	45	13.6	4	15.5	3	8.2
	No	208	5.7	222	9.7	33	8.6	109	3.2
Musculoskeletal disorders including bone disease	Yes	41	11.5	62	16.0	5	9.5	10	10.7
	No	183	5.7	205	8.6	32	9.3	102	2.6
Spinal abnormality (lower back problems, arthritis)	Yes	10	10.6	19	16.3	2	21.4	1	0.0
	No	214	6.6	248	9.9	35	8.6	111	3.4

[1] Question from medical record abstraction form. Evaluation by staff at patient's center.

NOTES: Data are for patients on treatment modality 1 year or more. SIP is Sickness Impact Profile. CPD is continuous peritoneal dialysis.

is based here on an evaluation by staff from the patient's center of there being at least slight limitation of physical activity (this is a more strict definition than used in other chapters). Once again, the ordering of modalities is similar to that shown in previous tables, although transplant patients are occasionally worse off than home hemodialysis patients.

In Table 12-B-4, total SIP scores are related to various everyday tasks according to treatment modality. The tasks in Table 12-B-4 have been arranged in order of difficulty. As shown, the SIP scores increase monotonically along with the difficulty of the tasks with dramatic intramodality differences. Again, modalities can be ordered roughly as they have been in previous tables. Transplant patients are usually the least functionally impaired followed by home hemodialysis, CPD, and in-center hemodialysis patients. The pattern of physical dimension SIP scores is similar but even more dramatic.

Most of the preceding tables have related SIP scores to various indicators that reveal the patients' more objective functional abilities. It is also evident, however, that SIP scores are related to various subjective aspects of the quality of life of end stage renal disease patients. In Table 12-B-5 SIP scores are related to various subjective quality of life indicators. In this table it is evident that SIP scores are related to subjective quality of life in an almost perfectly predictable manner—the worse off the patient, the higher the SIP scores. Also predictable is the ordering of treatment modalities from best to worst.

Table 12-B-6 shows the correlation between various quality of life indicators analyzed in Chapter 6 and total SIP scores. Given the categorical nature of the quality of life variables and their varying degrees of dysfunctional relevance, the results are quite good. In general, the highest correlations are with the Karnofsky Index, and the lowest are with the overall life satisfaction indicator.

Finally, the relationship of SIP scores to a wide variety of variables included in the NKDKTS is shown in Table 12-B-7, once again by treatment modality. Although the magnitude of these correlations is important, the sign of the correlation is also very instructive. The following associations are noteworthy:

- High SIP scores are positively related to the number of comorbid conditions.
- SIP scores are negatively related to education.
- SIP scores are negatively related to both personal and family incomes (i.e., people with higher incomes are less functionally limited).
- SIP scores are negatively related to weekly square metal hours of dialysis (i.e., the more square meter hours of dialysis the lower the patient's SIP score).
- SIP scores are positively correlated with total number of bed disability days.
- The more strained a patient's marriage, the higher the SIP score.
- The greater the weight gain between checkups, the higher the patient's SIP score.
- The worse the patient feels socioemotionally, the higher the SIP score.
- The more confined a patient is in terms of mobility, the higher the SIP score.
- The more help the patient needs in activities of daily living, the higher the SIP score.

The results presented in this appendix confirm that the Sickness Impact Profile is a robust, sensitive, and valid measure of perceived sickness-related behavioral dysfunction. With few exceptions, the relationship between SIP scores and various measures of functional ability and quality of life are in the predicted direction. The sensitivity of the SIP in differentiating patient groups or in identifying significant correlations is remarkable. In fact, its multidimensional nature allows it to be utilized with factors that are only secondarily related to its content area. In addition, the ordering of modalities in terms of best to worst is also impressively consistent.

Table 12-B-4

Mean total SIP scores for patients with end stage renal disease who have trouble performing selected everyday tasks, by current treatment modality and task

Did you (the patient) have trouble with the following tasks because of your health?	Response	Number of cases	Home hemodialysis	Number of cases	In-center hemodialysis	Number of cases	CPD	Number of cases	Transplant
Bending, lifting, or stooping	Yes	91	15.4	142	20.6	47	17.0	25	12.7
	No	193	6.8	193	9.1	34	9.2	119	4.0
Traveling unassisted in community	Yes	34	23.1	84	24.2	25	22.0	11	16.2
	No	251	7.7	253	10.3	56	10.0	132	4.6
Walking without help via person, cane, crutches, walker, artificial limbs, or braces	Yes	31	24.3	73	25.7	16	22.7	12	14.2
	No	255	7.7	264	10.7	64	11.4	132	4.7
Eating, dressing, bathing, or using the toilet	Yes	12	34.3	30	32.4	12	23.4	3	18.5
	No	274	8.4	307	12.1	69	12.0	141	5.2

NOTES: SIP is Sickness Impact Profile. CPD is continuous peritoneal dialysis.

Table 12-B-5

Mean total SIP scores for patients with end stage renal disease, by current treatment modality patient group and selected patient quality of life evaluations

Patient question	Response	Number of cases	Home hemodialysis	Number of cases	In-center hemodialysis	Number of cases	CPD	Number of cases	Transplant
How satisfied are you with your life as a whole these days?[1]	Satisfied	197	7.7	226	12.1	57	11.3	114	4.1
	Neutral	54	10.5	56	15.4	13	13.0	18	8.9
	Dissatisfied	34	18.6	52	19.0	11	26.8	11	15.2
Taking all things together these days are you	Very happy	88	5.7	79	9.1	19	8.9	68	3.4
	Pretty happy	165	9.5	203	13.8	52	13.8	66	6.6
	Not too happy	31	20.2	50	21.6	10	22.4	7	14.3
Comparing your health with that of other people your age, would you say your health is	Better	25	6.4	50	10.8	10	8.0	17	3.1
	About the same	86	6.8	116	11.5	21	8.4	67	3.4
	Poorer	169	11.3	159	16.4	49	16.9	59	8.6
Are you now able to work for pay	Full time	87	3.9	54	6.1	11	5.2	86	2.3
	Part time	81	8.0	70	9.7	9	9.6	20	7.4
	Not at all	116	14.8	207	17.4	61	15.8	37	12.0
How satisfied are you with your current sexual activity?[1]	Satisfied	115	7.9	127	11.2	23	11.8	80	5.3
	Neutral	52	9.2	78	12.9	23	11.6	36	5.4
	Dissatisfied	99	11.3	98	18.3	26	17.0	22	7.0
How have you been feeling in general during the past month?	Excellent spirits	27	4.9	30	7.0	2	8.5	29	2.3
	Very good spirits	64	6.8	74	11.2	21	8.9	36	3.4
	Good spirits mostly	100	8.2	123	11.2	33	12.8	37	6.2
	Up and down spirits a lot	73	11.4	88	19.5	18	17.2	35	7.3
	Low spirits mostly	15	21.1	15	23.9	4	18.2	5	14.7
	Very low spirits	7	27.1	8	25.5	3	33.4	2	23.0

[1] Collapsed from 7-level scale (1, 2, 3 = Satisfied; 4 = Neutral; 5, 6, 7 = Dissatisfied).

NOTES: SIP is Sickness Impact Profile. CPD is continuous peritoneal dialysis.

Table 12-B-6

Pearson correlation coefficients for indicators of quality of life and total SIP scores, by current treatment modality patient group

Quality of life indicator	Number of cases	Home hemodialysis	Number of cases	In-center hemodialysis	Number of cases	CPD	Number of cases	Transplant
Functional impairment (Karnofsky Index)[1, 6]	280	–.53	325	–.50	80	–.50	134	–.54
Ability to work[2]	284	–.50	331	–.40	81	–.40	143	–.59
Well-being[3, 7]	286	–.43	337	–.39	81	–.54	144	–.45
Psychological affect [4, 8]	280	–.46	330	–.49	78	–.53	143	–.40
Life satisfaction[5, 9]	285	–.36	334	–.24	81	–.47	143	–.42

[1] Scored as 1 = poor, through 10 = good.

[2] Scored as 0 = unable to work, 1 = able to work.

[3] Scored as 2.1 = low well-being, through 14.7 = high well-being.

[4] Scored as 1.0 = negative affect, through 7.0 = positive affect.

[5] Scored as 1.0 = dissatisfied, through 7.0 = satisfied.

[6] The correlations with the SIP physical dimension by modality in order are –.59, –.58, –.58, and –.61.

[7] The correlations with the SIP psychosocial dimension by modality in order are –.45, –.52, –.51, and –.46.

[8] The correlations with the SIP psychosocial dimension by modality in order are –.46, –.44, –.55, and –.39.

[9] The correlations with the SIP psychosocial dimension by modality in order are –.38, –.29, –.42, and –.45.

NOTES: All coefficients are significant at the .001 level. SIP is Sickness Impact Profile. CPD is continuous peritoneal dialysis. These indicators of quality of life are the same as those described in previous chapters.

Table 12-B-7

Pearson correlation coefficients for patients with end stage renal disease, by current treatment modality patient group, selected patient response characteristics, and total SIP scores

Description	Number of cases	Home hemodialysis	Number of cases	In-center hemodialysis	Number of cases	CPD	Number of cases	Transplant
Comorbidity index (number of comorbid conditions: 0-10)	283	***.31	332	***.29	81	***.38	139	***.18
School years completed (0-17)	285	***–.30	335	***–.17	81	–.13	143	+–.13
1981 personal income (labor income in dollars)	280	***–.25	328	***–.18	78	**–.28	137	***–.30
1981 family income[1]	256	***–.21	292	*–.11	69	+–.17	127	**–.21
Dialysis meter hours per week (square meter size of dialyzer times weekly hours on dialysis)	270	*–.14	326	*–.11	—	N/A	—	N/A
Days (at least partially) confined to bed in last 6 months	283	***.44	326	***.23	78	***.38	144	***.30
Kidney disease is strain on current marriage (married patients only)	195	**.18	151	**.22	53	.01	83	*.22
Higher than wanted weight gain between care visits	286	*.11	336	*.11	81	.07	143	+.13
Felt helpless, sad, etc., during past month	286	***.56	338	***.35	81	***.40	143	***.37
In bed or chair of day because of health	285	***.59	337	***.59	81	***.55	144	***.63
Need help eating, dressing, bathing, or using toilet because of health	286	***.57	337	***.51	81	***.42	144	***.27

[1] This aggregate dollar income measure includes any 1981 labor earnings (before taxes) of all household members plus annualized imputations of any benefits (e.g., social security benefits) they are receiving. Other income from assets (e.g., dividends and interest) is not included.

Significance levels are as follows:
+p ≤ .100
*p ≤ .050
**p ≤ .010
***p ≤ .001

NOTES: SIP is Sickness Impact Profile. CPD is continuous peritoneal dialysis. N/A = Not applicable for these modality patient groups.

Rehabilitation

Chapter 13.
Labor force participation

Introduction

Because of the importance of work in the lives of people, one of the criteria by which the effectiveness of medical therapies can be judged is their ability to facilitate this aspect of social functioning.[1] The impact of disease on the ability to work obviously depends on the nature and extent of the disease as well as on the nature of the work to be performed. But the complexity of the phenomenon is even greater than this because the ability to work does not necessarily imply that a person will work. The decision to work, especially for a disabled person, depends on many factors, such as what they can expect to gain from working, what the impact on their family will be, how working might affect their benefits from social programs, and whether they can find work in their usual occupation. Thus, in assessing the impact of a medical therapy on working, all of these factors must be considered so as not to confuse their impact with that of the therapy itself.

Throughout the 1960's as maintenance dialysis became an increasingly prevalent form of therapy for end stage renal disease (ESRD), only selected patients underwent dialysis or transplantation because the medical resources involved were scarce and had to be rationed. Selection was often made by committee, and one of the criteria reportedly used by clinicians was the likelihood of vocational rehabilitation (Katz and Proctor, 1969; Fox and Swazey, 1974; Abram, 1972; Schupak et al., 1967; Evans et al., 1981). The extension in July 1973 of Medicare benefits to all eligible ESRD patients removed this explicit focus on rehabilitation. It has been argued (Held and Pauly, 1979), however, that return to work remained one of the overall objectives, if an ambiguous one, of the ESRD program. Recently the rehabilitation of ESRD patients has received considerable attention, both in the report of the Office of the Inspector General (Bean et al., 1980) and by the establishment in 1981 by the Health Care Financing Administration of a special National ESRD Patient Rehabilitation Task Force. This reemphasis on rehabilitation as an outcome of the program no doubt derives in part from the accelerated increases in the total costs of the program. As the ESRD program has consumed a greater and greater share of medical resources, questions about its benefits arise; one of which is the return to normal functioning.

The treatment of end stage renal disease and the associated impact on the ability of and incentives for ESRD patients to work provide a unique illustration of the complexity of the work decision. Although ESRD is a chronic and severe illness with high treatment costs, it may often but does not always limit the ability to work. There are literally thousands of people on dialysis or with a transplanted kidney who lead apparently ''normal'' lives.[2] That is, they function socially very much as they did prior to the onset of the disease. Yet, there are also many people for whom the disease is totally debilitating. And, of course, there are perhaps even more people in the middle, those for whom ESRD imposes limitations on activity but does not totally rule out work or other social activities. In addition to and because of its medical uniqueness, ESRD exhibits other unique features because of the special consideration it receives under public policy. First, it is the only specific disease that the Federal Government covers under Medicare for those under 65 years of age. Second, under the Federal Government's disability program, ESRD is apparently treated as prima facie evidence of disability: For those on dialysis it is difficult to deny disability. Thus, dialysis patients have a very high probability of receiving a disability entitlement if they seek it (Bean et al., 1980; National ESRD Rehabilitation Task Force, 1982). Obviously, being entitled to disability benefits when not working lessens the net gains from working.

The ultimate objective of the investigation begun in this chapter is to disentangle the various influences of treatment modality, health limitations, and social programs on the decision to work of ESRD patients. The results reported here do not fully address all of these possible influences. Among the specific questions that are addressed are the following:

- Are some treatment modalities associated with labor force participation to a greater extent than others?
- To what extent does health alone rule out working for ESRD patients?
- To what extent do case-mix differences account for intermodality differences in the likelihood of working?

The chapter begins with a background section, discussing prior studies of ESRD patients who work and more general studies of the impact of health and social programs on the decision to work. The analytical approach used to organize the empirical investigation is discussed in the next section, and the results of the investigation are presented in the final section. The results are then summarized and their implications are discussed.

Background

Previous work, both on the employment status of end stage renal disease (ESRD) patients and on the impact of health on the decision to work of a more general population, provides an important starting point for this investigation. For purposes of this study, prior studies of the employment status of ESRD patients fall into three general catagories—small sample studies prior to 1977, studies in other countries, and more recent studies of larger samples. For obvious reasons, studies falling into the first two categories are often of limited relevance to current policy in the United States. Furthermore, results of the studies in all three categories are often less useful because of the lack of attention paid to potential differences in case mix among modalities. The value of the more general literature on work and health status is that it suggests the appropriate multivariate models for dealing with the case-mix issue. Each of these literatures is discussed in turn in this section.

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[1] "Work" in this paper means participation in the paid labor force.

[2] It should always be remembered that normality in social functioning does not mean that their lives are exactly the same as others—they are not. Dialysis patients must devote a substantial portion of their time to the dialysis treatment, and transplant patients must take immunosuppresive drugs which often have negative side effects on their health and well-being.

Prior to 1977, there were a number of studies of the employment status of ESRD patients. The results of these studies have been summarized in Chapter 1 (Table 1-1). A review of these studies revealed two important patterns—the proportion of patients working is often strikingly high (well over 40 percent); and patients who dialyze at home exhibit higher rates of employment than those who dialyze in facilities.

Although the results of these early studies were encouraging news about the potential benefits of ESRD treatment, a number of limitations of these studies are apparent. First, for the most part, the earliest studies of work among ESRD patients were small studies, often of only one treatment modality or limited to a small sample of patients. Also, these studies were undertaken while the Federal ESRD program was beginning its dramatic expansion. Second, three of the larger studies (Disney and Row, 1974; Brunner et al., 1976; Tews et al., 1980) are for populations outside the United States. Besides these reasons, the results are of limited relevance today because the measured rates of employment did not differentiate by case mix of the population, which may differ today from those in the studies.

Results from the recent large sample study of the U.S. dialysis population, the 1978 Home Dialysis Study, underscore the importance of changing case mix. In comparing the characteristics of the 1967 ESRD population (less than 1,000 patients) and the 1978 ESRD population (between 30 and 40 thousand patients), Evans et al. (1981) found significant changes in the composition of the populations. The 1978 population was on the average less male, less white, less educated, and older than the 1967 population. There had been a substantial shift to a population more representative of the total U.S. population. This shift was largely the result of the extension of Medicare benefits to all ESRD patients covered under social security. Not surprisingly, this change in the population has changed the average rates of employment. In 1967, 42 percent of patients were working, but by 1978 this had fallen to approximately 18 percent. Furthermore, only 13.7 percent of facility patients were working in 1978, a rate far below the 32 percent of home patients who were working (Bryan et al., 1978). Whether these falling rates of labor force participation are solely or even principally the result of the change in the composition of the population (i.e., case mix) is unknown.

Another recent study (Gutman et al., 1981), conducted in 1979 and based on employment status as reported by facility personnel (i.e., not by patients directly), found significant levels of disability in the ESRD dialysis population. Some 45 percent of all patients were found to be limited in their activities to at most self-care. And even for the group most likely to be working—nondiabetic males aged 21-59 years—only 39 percent were working. Although these figures accord with the general impression that the average health status of the ESRD patient population has been worsening, they do not separate the impact of case mix from other factors.

There has been only one multivariate analysis (Evans, 1979) of the determinants of ESRD patient employment status. This analysis used the data from the 1978 Home Dialysis Study and examined employment status as one of a larger set of outcomes in comparing treatment modalities. The results for employment status are consistent with those for the general population: Those who were younger, male, more educated, and in good health were more likely to be working, other things being equal. Nonetheless, even after controlling for the preceding variables as well as for race, marital status, and other psychosocial factors, home patients were found to be significantly more likely to be working. Thus, case-mix differences did not totally account for differences in employment status in facility versus home patients. The multivariate model used in this analysis was limited, however, in that the data were not available to control directly for the potentially important effects of expected wages and expected social program benefits.

In addition to the preceding studies of the ESRD population, a number of studies from the health economics literature of the relationship between health and employment in the general population are of relevance. They suggest the types of variables that should be included in a multivariate model of employment status. The basic economic model of labor force participation assumes that, other things being equal, people participate or work if the benefits from working (both the wage and nonpecuniary features) exceed the costs of working (the benefits of not working both pecuniary and psychic). Thus, the structural multivariate model predicting employment should include the expected wage as well as indicators of the costs of working, such as forgone public benefits and family characteristics.[3] Furthermore, since leisure time (i.e., hours spent not working) is a valued good, one should expect its consumption to be related to overall wealth (or nonlabor income), implying that a structural model should include a wealth measure. Historically, separate models of the labor force participation of males and females have been developed. This was because the labor force participation rates were so vastly different for the two groups, and the factors associated with the value of not working were seen as different. For example, because of traditional sex roles, the number and ages of children in the home were seen as having a greater impact on female labor force participation.

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[3] The term "structural" here is used in its econometric sense—to denote a causal model with possible reciprocal causation (i.e., it may include endogenous factors, such as health affecting employment). This is in contrast to a "reduced-form" model where the dependent variable is predicted solely on the basis of exogenous factors.

More recently, although the general models for male and female labor force participation have not changed, there has been greater interest in the impact of health on labor supply. Grossman and Benham (1973) estimate such a structural model of labor force behavior including a health measure. They found that good health increases the probability of working both because it increases the expected wage from working and because it increases the available time for working. Subsequent studies (e.g., Berkowitz and Johnson, 1974; Parsons, 1977) have also substantiated the importance of health in explaining labor supply. However, as will be emphasized in the next section, the definition and measurement of health is not a straightforward matter. Furthermore, it has been shown that the way in which health is measured can have a significant impact on the relation between work activity and the other factors affecting it, such as expected wages (Lambrinos, 1981).

Another relevant body of economics literature concerns the impact of social programs such as income maintenance schemes, the social security disability program, and the social security retirement program on the decision to work. For example, although health is by far the most common reason given for retirement, it has been shown (Boskin and Hurd, 1978) that the level of expected social security benefits is also an important explanatory variable. In addition, evidence from the Social Security Administration's disability program (Halpern, 1979) suggests that the level of disability benefits is an important determinant of the number "disabled." In other words, disability and health, though undoubtedly important factors in the decision to work, do not always dictate the choice.

In summary, the end stage renal disease literature on the return to work suggests the importance of case-mix and treatment modality in understanding differences in patient's work behavior. The economics literature on labor supply points out the several factors that need to be accounted for in a multivariate model of the work decision. The analytical approach described in the next section represents an attempt to incorporate this broad set of factors within the limitations imposed by the data collected in this study.

Analytical approach

Conceptual issues and definitions

Although the general meanings of the terms "health" and "disability" are probably clear to most researchers, in specific application they are used almost interchangeably by some researchers and disciplines, but for others they are distinctly different. The discussion here will follow to a large degree the distinctions set forth by Nagi (1976; 1979) among pathology, impairment, functional limitations, and disability. Briefly, these terms can be defined as follows:

- *Pathology* is the existence of disease in an individual.
- *Impairment* is the subnormal functioning of a human body system because of the existence of disease.
- *Functional limitations* are the restrictions in the ability of an individual to carry out normal tasks because of the existence of impairment.
- *Disability* is "a form of inability or limitation in performing roles or tasks expected of an individual within a social environment" (Nagi, 1979).

Furthermore, Nagi has drawn a distinction between work disability and independent living disability. Work disability concerns limitations with regard to activities performed on the job, and independent living disability is relative to the more basic activity of daily living. It should be apparent from both the definitions and casual observation that the links among these concepts are approximate and not deterministic. That is, pathology does not imply impairment, nor does impairment necessarily imply functional limitations, and so on.

Economists working in this area have often, but not always, distinguished between "health" and "disability." The former is treated as a theoretical concept representing a variable that is impossible, or at least difficult, to observe directly. It and its effects can be indirectly observed as follows:

- Subjective evaluation—Asking for self-reported health (excellent, fair, etc.).
- Objective indicators—Death or days ill.
- Subjective indicators—Self-reported functional limitations or work disability.

Economists have tended to define "disability" as work disability as defined above, thus reflecting an interaction between physiological conditions and work requirements. On the other hand, this theoretical concept of health, as used by economists, is very much a characterization or summary measure of physiological functioning and is meant to exclude work requirements. But can such a concept be unidimensional? Who is healthier, one who is blind or one who is crippled? Since such a ranking cannot be made, health must be a multidimensional concept. To this point, neither the theoretical nor empirical analyses of economists has emphasized this multidimensionality. The analyses reported here will not resolve this problem, but it is important to recognize these distinctions and the complexity of the underlying issues.

As defined above, having work disability does not necessarily imply that an individual will not work, only that the probability of working will be lower. A number of useful distinctions can also be drawn among concepts relating to work. The discussion here will distinguish among the several concepts with regard to work activity, but the analyses that follow will focus on only one. The respondents were asked to place themselves in one of the following nine categories in the standard survey question that was used to define employment status:

1. Employed full time.
2. Employed part time.
3. Employed but temporarily laid off.
4. Unemployed, looking for work.
5. Unemployed, not looking for work.
6. Unable to work because of health (disabled).
7. Homemaker.
8. Student (full time).
9. Retired.

If they claimed to be employed (categories 1-3) they were asked about their level of work activity; that is, how many weeks per year and hours per week they usually work.

Based on their employment status and level of work activity, two other concepts can be defined: labor force participation and labor supply. Following the U.S. Department of Labor definition, the former refers to those individuals in the first four categories of employment status. The latter concept of labor supply refers to the amount of labor (either weeks or hours per year) supplied to the market. Only those in the first two employment status categories will have positive labor supply. Those in categories 3 through 9 will have zero labor supply. The analysis and results reported here focus on labor force participation and not labor supply or on finer distinctions of employment status. These latter topics will receive attention in future analyses.

The decision to work

Previous analyses have found that home dialysis patients are more likely to be working than facility dialysis patients. Why might this occur? Underlying case-mix differences may be the reason, but even multivariate analysis (Evans, 1979) has shown that age, sex, race, education, and physiological (i.e., comorbid) conditions do not totally remove the effect of being on home dialysis. Despite this empirical result, it is difficult to construct individual scenarios under which home dialysis always increases the likelihood of working. The net effect of the various offsetting factors is not at all clear.

Consider two individuals of identical age, sex, race, education, and overall health status, but one dialyzes in the home and the other in the facility. The main benefit of home dialysis for the potential to work is that it gives the individual greater flexibility in terms of scheduling. For example, evening or night dialysis can be used if the person holds a daytime job. On the other hand, if evening dialysis services are offered by facilities, then it is not obvious that home dialysis facilitates working more than in-center dialysis.

There may, however, be some difference in terms of the amount of time required for home dialysis and that required for facility dialysis. Home dialysis times may be longer because the individual is involved in preparation and cleanup; this is not the case when dialysis is done in the facility. On the other hand, travel to and from the facility takes time and would offset this difference.

Clearly, the lack of availability of night in-center dialysis may mean that some individuals could not work at their usual jobs unless they did dialyze at home. But home dialysis may not be feasible or economically desirable for those lacking a spouse or relative or other person to act as an aide. Having to pay for an aide would obviously reduce the desirability of working for the home dialysis patient if the patient has to pay part of the cost out-of-pocket. Again, the net effect of all of these offsetting factors is not obvious.

Less is known about the employment status of transplant versus that of the dialysis patients. Clearly, because transplant patients do not face the constraint of three lengthy dialysis sessions per week, they will have more available time to devote to labor market activity, and this would tend to encourage labor force participation. On the other hand, if their health status were poorer on the average than that of dialysis patients (e.g., they might be more susceptible to infection), then their average labor force participation might be lower. Another important factor concerns eligibility for Medicare benefits as well as social security disability benefits. Kidney transplant patients are now eligible for Medicare benefits for only 3 years after the operation.[4] When these benefits expire, they obviously have a great incentive to return to the labor force to get health insurance coverage as well as to meet the costs of their medical expenditures. Also, because it seems likely that transplant patients are less likely to qualify for social security disability benefits, they would more likely be working for this reason as well.

Recently, a new form of dialysis—continuous peritoneal dialysis (CPD)—has become available to end stage renal disease patients. This treatment modality differs in many ways from hemodialysis, either performed in-center or at home. The CPD patient does not have to sit three times a week for lengthy (3-4 hours) dialysis sessions, but instead must dialyze for short intervals (lasting 20-30 minutes and called ''exchanges'') four times per day. A priori, it is not obvious whether this form of treatment would facilitate or hinder work, as compared with home hemodialysis or in-center hemodialysis. Since the total time spent dialyzing per week might well exceed that of hemodialysis patients, there is no obvious greater availability of time that would facilitate working. It would seem to depend greatly on one's job or occupation and on whether the work could be performed between or during the exchanges. Furthermore, because sterile technique is very important in this modality, certain job settings could be hazardous. Thus, the net effect on work as compared with hemodialysis is not obvious.

As compared with transplantation, however, CPD patients should be less likely to work because less total time is available for work. Recognizing the newness of CPD as a therapy as well as its currently limited diffusion around the country, the initial empirical evidence is not favorable with regard to employment. Lindsay and associates, in studies comparing CPD and home hemodialysis patients, have found that employment is more of a problem for CPD patients and that the use of CPD as a treatment modality hampers an individual's ability to return to work, especially if the patient is male or in the older age group (Burton et al., 1980; Lindsay et al., 1981; Richmond et al., 1982). Even with regard to housework, CPD patients were found to show more impairment.

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[4] Aiming to encourage transplantation, Public Law 95-292, enacted in 1978, extended the period of post-transplant entitlement from 12 months to 36 months.

The preceding discussion not only suggests the complexity of the issue but also points to a problem of causal ordering. Do individuals choose (or are assigned) treatment modality in a first-stage decision and then in the second stage decide whether or not to work given that modality? Or do they choose modality with an eye towards working or not working? If the latter is true, then the decision is a joint one, and it is inappropriate to interpret causality as running from modality to work. At a minimum, this introduces a selection bias into any estimates and, at a maximum, it implies that the statistical model used here is inappropriate. At this preliminary stage, however, the analyses performed here will assume, by treating modality as an exogenous determinant of labor force participation, that the decision is a two-stage process. A result that modality is significantly related to participation might be entirely the result of selection bias, and thus it could not be ruled out that the decision is a joint one and that the result is spurious. On the other hand, if modality is not related to participation, then it is less likely that the jointness of the decision is affecting the results. Clearly, the possible interaction between labor force participation and choice of modality raises difficult questions about both appropriate statistical technique and correct inference.

Briefly, the data came from a cross-sectional survey conducted in 1981-82 of 859 patients from 11 dialysis and transplant centers around the country. The centers were purposively selected to represent a diverse set of characteristics, but the patients were chosen randomly within the centers. In addition, the sample was stratified by treatment modality—home hemodialysis, in-center hemodialysis, continuous peritoneal dialysis, and transplantation—and the total number selected in each modality was set in accordance with the objectives of the study. The final counts for each modality were 287 in home dialysis, 347 in in-center dialysis, 81 in CPD, and 144 in transplantation. The sample design and survey instruments are discussed in more detail elsewhere in this report.

Results

The focus of this analysis is the relation between employment status and treatment modality. The nine categories of employment status were defined above. This analysis, however, focuses on only one important dimension of employment status—labor force participation. Again, sample members are labor force participants if either they are employed full time, employed part time, employed but laid off, or unemployed but looking for work. Nonparticipants are either unemployed not looking for work, disabled, homemakers, students, or retired. In this sample, one-third of the end stage renal disease (ESRD) patients were participants. The definitions, means, and standard deviations of the variables that will be used in the analysis are shown in Table 13-1. Although the table is self-explanatory, it should be noted that at this stage the multivariate analysis will use self-reported health as the only indicator of health or disability. Aside from its generality, the use of this particular measure reduces the number of observations that would be lost because of missing values. Along this same line, note that wealth dummies include a category for those who did not provide an estimate; the use of this dummy keeps the observations in the analysis rather than forcing their exclusion because of a missing value.

Table 13-1
Definitions, means, and standard deviations of the variables used in the analysis

Variable	Definition	Mean	Standard deviation
Labor force participation	1 if the individual is employed or is unemployed and seeking work,	.33	—
	0 otherwise.	.67	—
Age	Patient age in years	47.5	14.6
Gender	1 if male	.55	—
	0 if female	.45	—
Married	1 if married, spouse present	.63	—
	0 otherwise	.37	—
Race	1 if white	.73	—
	0 otherwise	.27	—
Education	Number of years of formal schooling	12.1	3.2
Self-reported health			
Excellent	1 if excellent; 0 otherwise	.12	—
Good	1 if good; 0 otherwise	.40	—
Fair	1 if fair; 0 otherwise	.37	—
Poor	1 if poor; 0 otherwise	.12	—
Self-reported wealth			
Less than $10,000	1 if less than $10,000; 0 otherwise	.38	—
$10,000-$24,999	1 if $10,000-$24,999; 0 otherwise	.12	—
$25,000-$49,999	1 if $25,000-$49,999; 0 otherwise	.11	—
$50,000-$99,999	1 if $50,000-99,999 0 otherwise	.11	—
$100-000-$199,999	1 if $100,000-$199,999; 0 otherwise	.07	—
$200,000 or more	1 if $200,000 or more, 0 otherwise	.04	—
Missing	1 if missing data, 0 otherwise	.17	—
Treatment modality			
Home	1 if on home dialysis; 0 otherwise	.33	—
In-center	1 if on in-center dialysis; 0 otherwise	.40	—
CPD	1 if on CPD; 0 otherwise	.10	—
Transplant	1 if a transplant; 0 otherwise	.17	—

NOTES: Based on a sample of 834, 25 observations from the original sample of 859 were excluded because of missing data.

In what follows, some descriptive tables are first presented to illustrate the general relation between ESRD and employment status as well as between employment status and particular modalities. These are followed by

Table 13-2

Percent of patients with end stage renal disease, by prior and current employment status and treatment modality

Treatment modality	Number of cases	Employed full time	Employed part time	Employed but temporarily laid off	Unemployed but looking for work	Unemployed not looking for work	Unable to work because of health disabled	Homemaker	Student full time	Retired
					Percent 1 year before dialysis					
All modalities	858	60.3	6.8	0.2	0.2	1.0	8.2	11.0	7.3	5.0
Home	287	64.1	5.9	0.0	0.0	0.3	8.4	11.1	7.3	2.8
In-center	346	58.4	8.7	0.3	0.6	1.7	8.7	11.3	2.9	7.5
CPD	81	55.6	4.9	1.2	0.0	1.2	14.8	9.9	2.5	9.9
Transplant	144	59.7	4.9	0.0	0.0	0.7	2.8	10.4	20.8	0.7
Chi-square significance = .0000										
					Percent current employment status					
All modalities	857	22.3	7.4	0.6	3.2	2.9	39.2	11.3	2.5	10.7
Home	287	26.8	9.4	1.0	2.4	1.0	35.9	12.2	3.5	7.7
In-center	346	13.0	7.5	0.3	2.9	3.2	46.2	9.8	0.9	16.2
CPD	80	13.7	2.5	0.0	0.0	7.5	47.5	11.2	1.2	16.2
Transplant	144	40.3	5.6	0.7	6.9	3.5	24.3	13.2	4.9	0.7
Chi-square significance = .0000										

Table 13-3

Number of patients with end stage renal disease, by prior employment status and current employment status

Current employment status		Prior employment status								
	Total	Employed full time	Employed part time	Employed, laid off	Unemployed, looking	Unemployed, not looking	Unable to work, disabled	Homemaker	Student full time	Retired
Total	857	517	58	2	2	10	70	97	59	42
Employed full time	191	152	5	0	0	0	4	1	29	0
Employed part time	63	36	14	0	0	0	2	6	4	1
Employed, laid off	5	5	0	0	0	0	0	0	0	0
Unemployed, looking	27	18	1	0	0	1	1	5	1	0
Unemployed, not looking	25	15	1	1	0	3	2	1	2	0
Unable to work, disabled	336	232	27	1	2	5	53	10	5	1
Homemaker	97	10	4	0	0	0	4	74	4	1
Student full time	21	6	0	0	0	0	1	0	14	0
Retired	92	43	6	0	0	1	3	0	0	39

the results of a multivariate analysis aimed at accounting for the differences across modalities.

Two cross-tabulations—current employment status with treatment modality and employment status prior to the onset of kidney treatment with treatment modality are presented in Table 13-2. Several important findings are apparent. First, as shown by the chi-square tests, there were and are significant differences in employment status across treatment modalities. However, the differences in current employment status are certainly more obvious: transplant patients are most likely (53.3 percent) to be participants, followed by home patients (39.6 percent), in-center patients (23.7 percent), and lastly CPD patients (16.2 percent). Before the onset of ESRD, that the overall average is 33 percent). In the literature review it was pointed out that previous studies had

Table 13-4

Number, percent, and labor force participation of patients with end stage renal disease, by pathology, functional limitations, and work disability

Item	Total sample		Labor force participation	
	Number	Percent	Yes	No
Pathology—Number of comorbid conditions				
0	386	45.8	166	220
1	225	26.7	68	157
2	120	14.2	32	88
3	56	6.6	9	47
4	20	2.4	2	18
5-10	39	4.6	3	36
Functional limitations because of health				
Stay indoors most or all of day	135	15.8	8	127
In bed or chair most or all of day	137	16.0	14	123
Trouble bending, lifting, stooping	455	53.4	98	357
Trouble walking one block or climbing one flight of stairs	308	36.2	51	257
Need assistance in walking	132	15.4	11	121
Need help in eating, dressing, bathing, or using toilet	58	6.8	4	54
Limited ability to reach	178	20.8	18	160
Limited ability to use fingers in grasping	183	21.4	25	158
Limited ability to use eyes for inspection	248	29.1	39	209
Limited ability to lift up to 10 pounds	283	33.2	37	246
Work disability				
Health keeps from working at job, working around house, or going to school	466	54.8	32	434
Health keeps from working for job for pay now	515	60.2	34	481
Health limits kind of work	454	53.1	40	414
Health limits amount of work	447	52.3	32	415
Now able to work for pay:				
Full time	239	28.2	210	29
Part time	182	21.5	74	108

NOTE: The total sample size implied by the first and second columns varies slightly among these measures because of missing values.

67.1 percent of those in the sample were labor force participants; after onset, only 33.5 percent were participants.[5] A simple calculation, using the age-sex-race participation rates for the general population, suggests that their prior labor force participation is remarkably like the general population (the predicted rate, based on the age-sex-race distribution would be 66.8 percent, as compared with the 67.1 percent for the sample).[6] Of course, the dramatic decline is the most notable feature of this table since the differences across modality might be entirely because of differences in case mix, that is, the composition of the samples.

Table 13-3 is a cross-tabulation of prior employment status with current employment status, ignoring differences in treatment modality. The manner in which the 50-percent decline in labor force participation occurs is illustrated in the table. For the most part, it is a matter of those who formerly held full-time jobs moving to the disabled category. In only a few instances are formerly disabled people able to return to work, although there are significant numbers of former students entering the labor force after the onset of kidney disease. Those who were homemakers prior to the onset of ESRD tend to be homemakers currently, and only a small percent of former workers become homemakers.

In the discussion of the analytical approach above, a distinction was made among the following concepts of disability: pathology, impairment, functional limitations, and work disability. Information was gathered on three of the four concepts. The cross-tabulation of these measures with labor force participation is shown in Table 13-4.

The figures in this table suggest two general observations. First, a very significant, but not overwhelming, proportion of the sample has severe functional limitations. For example, 53.4 percent have trouble bending, lifting, or stooping. Second, among those with the more comorbid conditions, functional limitations, or disability, the likelihood of labor force participation is lower (recall established a strong link between disability (or health) and labor force activity. Although the results shown in this table underscore the importance of this relationship, they also point to the important fact that it is exceedingly difficult to rule out labor force participation on the basis of health alone. A key finding in this table is that many ESRD patients are able to participate in the labor force despite significant comorbidity or functional limitations. For example, 455 members (or 53.4 percent) of the sample (of 859) claimed to have trouble bending, lifting, or stooping. But despite this functional limitation, 98 of the 455 were labor force participants. For the type of analysis attempted here, there is a certain appeal in trying to divide the ESRD population into two groups—those who are clearly unable to work because of health problems and those who can work. Then one can proceed to look at how other incentives (wages and disability) affect the behavior of the latter group. The results in Table 13-4 suggest that this is a false dichotomy and that work activity simply cannot be ruled out on the basis of health alone.

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[5] This figure differs slightly from that in Table 13-1 because of the exclusion of some observations for missing data in Table 13-1.

[6] This calculation was a simple weighted average where the weights are the proportion of the sample in each of 24 cells (two race categories by two gender categories by six age categories). These weights were multiplied by the appropriate national labor force participation rate for the cell, and then the products were summed over all the cells. The result is an expected labor force participation rate for the sample.

On the one hand, this is not particularly surprising because everyone is aware of remarkable cases of quadriplegics and other seriously ill people participating in the labor force. On the other hand, it raises some question about what it means to decide on medical grounds that a person is unable to work, as is done in the social security disability program. The work disability questions at the bottom of the table show that those who indicate work disability are much less likely to be working than the average sample member (for whom the probability of working was .33).[7]

To examine the multivariate relationship between labor force participation and modality (as well as other factors) a wide variety of statistical techniques are available. For reasons of simplicity and convenience, multiple regression is used for the analyses reported here. Because the dependent variable in the regression is dichotomous (a 1-0 dummy with 1 = labor force participation), these equations are "linear probability models."[8] Coefficient estimates from several multiple regressions predicting labor force participation are presented in Table 13-5. The coefficients are interpreted as partial derivatives that show the change in probability of labor force participation for a one-unit change in the independent continuous variable, such as age and education. For the other variables, which are categorical and are expressed as dummy variables, the coefficients represent the increase in probability that is the result of membership in the specified category, as compared with the one excluded category. For example, in the regression in the first column, the excluded category is in-center patients. The probability of labor force participation for them is .236, and relative to this group, home patients are .162 on the average more likely to be labor force participants. The excluded categories for the other multiple dummies in the equation were Health-Poor, and Wealth-$0-9,999. For example, in the third column, those with excellent health were more likely (by .353), other things being equal, to be participants than those in poor health. The adjusted R^2 statistic reported at the bottom of the table is the standard measure of goodness to fit in the regression model. It indicates the proportion of variance in the dependent variable accounted for by the independent variables, adjusted for degrees of freedom (i.e., the number of independent variables used). The statistic is less meaningful for the linear probability model than in the standard regression. The first regression (column 1) essentially shows the mean differences in labor participation among the four treatment modalities. Clearly, there are significant differences between particular modalities (home versus in-center and transplant versus in-center) and among the four modalities as a group, as reflected in the joint F-statistic at the bottom of the table.[9]

The first regression does not control for any case-mix differences, but the second regression introduces a small set of basic demographic controls. The impact of these controls on the modality coefficients is substantial. Although the modality dummies remain significant as a group, the difference between home and in-center patients is no longer significant. The difference in the likelihood of working for transplant patients versus in-center patients is more than cut in half, but still significant. The difference between home and in-center patients is not only reduced by more than one-half but also becomes statistically insignificant. And with these controls, CPD patients are significantly less likely to be working than in-center patients. Thus, overall, case-mix differences account for a good portion of the apparent differences among modalities in the likelihood of labor force participation.

The regressions in the third and fourth columns show the impact of the introduction of a broader set of exogenous factors into the model. In general, intermodality differences are reduced even further, although the modality dummies remain significant as a group (largely because transplants are more likely to be participants).

The coefficients on the control variables are more or less what one would expect. Older patients (over age 40) are less likely to be participating in the labor force, and males are more likely than females. White patients are

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[7] Note that 34 members of the sample who indicated that they were labor force participants also said that their health kept them from working on a job for pay now. Because 25 of the 34 were employed (rather than employed but laid-off or unemployed and looking for work) and gave detailed descriptions of their current job, it appears likely that the inconsistency arises because of a misunderstanding of the question on health affecting working.

[8] The statistical problems with the linear probability model (i.e. heteroskedasticity and non-normal errors) are well known (Goldberger, 1964). However, in application when the mean of the dependent variable falls between .2 and .8, this convenient model yields results remarkably similar to more appropriate models, such as logit and probit (Gunderson, 1974; Werner et al., 1979). In practice, the linear probability model appears to understate the standard errors on the order of 10-20 percent as compared with a probit model (Garrison, 1981). Thus, marginally significant variables here might not be with a probit model.

[9] The joint F-test is used to test the hypothesis that a set of variables makes a statistically significant contribution to the explained variance of the equation. In this table the set is the three modality dummies, and thus the test is whether "modality" makes a difference. How individual dummies differ from in-center dialysis, the excluded group, is indicated by their specific F-statistics. See Pollisar and Diehr (1982) for a useful discussion of the appropriate use of dummy variables.

Table 13-5

Labor force participation regressions for four treatment modalities: Reduced-form results for the entire sample

Item	1	2	3	4
Constant	***.236 (89.5)	.213 (1.8)	**–.476 (8.2)	*–.342 (4.0)
Home	***.162 (19.3)	.062 (2.5)	.043 (1.4)	.039 (1.1)
CPD	–.074 (1.7)	*–.119 (4.5)	–.095 (3.2)	–.101 (3.7)
Transplant	***.292 (40.6)	**.125 (6.6)	*.097 (4.3)	*.095 (4.1)
Age	—	.008 (1.5)	*.013 (4.3)	.010 (2.3)
Age^2	—	**–.0002 (6.6)	**–.0002 (9.4)	**–.0002 (6.8)
Gender (male)	—	***.165 (28.8)	***.160 (30.0)	***.147 (25.0)
Married	—	–.014 (.2)	–.031 (.9)	–.054 (2.6)
Race	—	*.076 (4.2)	.007 (.03)	–.013 (.1)
Education	—	—	***.034 (48.5)	***.029 (33.1)
Health-excellent	—	—	***.353 (33.1)	***.342 (31.2)
Health-good	—	—	***.217 (19.9)	***.213 (19.3)
Health-fair	—	—	*.116 (5.9)	*.112 (5.5)
Wealth-$10,000-$24,999	—	—	—	.092 (3.6)
Wealth-$25,000-$49,999	—	—	—	.061 (1.4)
Wealth-$50,000-$99,999	—	—	—	.099 (3.6)
Wealth-$100,000-$199,999	—	—	—	**.164 (6.8)
Wealth-$200,000 or more	—	—	—	*.174 (5.2)
Wealth-missing	—	—	—	.016 (.1)
Adjusted R^2	.06	.16	.25	.26
Joint F-test on modality	***19.3	**5.8	**3.8	**3.9

NOTES: *Significant at .05 level.
**Significant at .01 level.
***Significant at .001 level.
Coefficients with *F*-statistics in parentheses.

more likely than nonwhite patients to be working, but the great majority of this difference appears to be because of differences in education and self-reported health status. Surprisingly, marital status has no significant impact on participation. This result may be due to the pooling of diverse race and gender groups in the equation. The more educated (who can generally expect higher wages) are significantly more likely to be labor force participants, and those in excellent, good, or even fair health are significantly more likely to be participants than those self-reporting poor health. Finally, greater family wealth is associated with higher labor participation, other things being equal. Those individuals from families with total wealth greater than $100,000 are over 15 percent more likely to be in the labor force than those in the lowest wealth category. At some point, the general expectation is that more wealth will begin to lead to lower labor force participation. Evidently, that point is above $200,000 for this sample.

The preceding results for transplants and CPD are in accordance with what was expected. The fact that the "home effect" was totally removed by the exogenous controls is more surprising. Because of the potential importance of this finding, a more detailed analysis is desirable. Pooling individuals from diverse race, sex, and age groups in the same regression yields a form of averaging of the effects for subgroups. To reduce this averaging, a comparison of home versus in-center patients is presented in Table 13-6, again using the linear probability regression, for four subgroups: all males aged 25-64, white males aged 25-64, all females aged 25-64, and white females aged 25-64. The gender groups were split because of established differences in their labor force participation. Separate regressions were not estimated for nonwhite patients because of having too few observations. Age was restricted to this range to remove students or those eligible for or approaching retirement.

The results in Table 13-6 show that being a home patient is positively associated with labor force participation for males and negatively associated for females. However, only for white males is the association statistically significant: Other things being equal, white males aged 25-64 on home dialysis are .154 more likely to be in the labor force than white males of this age range on in-center dialysis. The raw means for this subgroup are .36 of in-center patients in the labor force and .59 of home patients. Thus, .154 of this .23 differential remains after introducing the case-mix controls in the regression.

More education, presumably reflecting higher expected wages, continues to have strong positive association in all four regressions. Better health is associated with higher participation for all groups as well. Being married significantly reduces the probability that a female dialysis patient will work or seek work, but it has no impact for males. Wealth shows no systematic relation to participation for males, but for females those from families in the mid-range are more likely to be participants than either the very poor (wealth less than $10,000) or the rich (wealth greater than $200,000).

Table 13-6

Labor force participation regressions for home versus in-center patients: Reduced-form results for selected subgroups

	Subgroup			
Item	All males aged 25-64	White males aged 25-64	All females aged 25-64	White females aged 25-64
Constant	*–1.18 (4.5)	–1.34 (3.8)	–.716 (2.1)	–.213 (.1)
Home	.117 (3.3)	*.154 (4.1)	–.037 (.4)	–.087 (1.7)
Age	.045 (3.6)	.044 (2.2)	.025 (1.4)	–.0008 (.001)
Age^2	–.0006 (4.8)	–.0005 (3.0)	–.0003 (2.2)	–.0001 (.09)
Married	–.025 (.1)	.036 (.2)	*–.143 (6.5)	**–.209 (8.1)
Race	.044 (.4)	— —	–.060 (.8)	— —
Education	***.043 (17.3)	***.054 (21.4)	***.039 (15.1)	**.037 (7.0)
Health-excellent	**.373 (9.3)	.292 (3.7)	**.358 (9.2)	.289 (3.4)
Health-good	**.307 (10.8)	**.294 (6.9)	*.207 (5.7)	**.339 (7.6)
Health-fair	.178 (3.8)	.200 (3.3)	.094 (1.2)	.234 (3.4)
Wealth-$10,000-$24,999	–.035 (.1)	–.029 (.1)	*.232 (6.2)	**.398 (11.3)
Wealth-$25,000-$49,999	–.004 (.001)	–.001 (.0001)	.075 (.7)	.141 (1.9)
Wealth-$50,000-$99,999	.112 (1.2)	.104 (.8)	.043 (.1)	.215 (2.5)
Wealth-$100,000-$199,999	–.002 (.0004)	–.065 (.3)	*.353 (6.4)	**.457 (9.8)
Wealth-$200,000 or more	–.003 (.001)	–.056 (.2)	.169 (.7)	–.010 (.002)
Wealth-missing	.031 (.1)	–.007 (.003)	.097 (1.6)	*.225 (5.9)
Adjusted R^2	.22	.22	.20	.25
Mean of dependent variable	.464	.501	.222	.236
Number of observations	267	188	225	140

NOTES: *Significant at .05 level.
**Significant at .01 level.
***Significant at .001 level.
Coefficients with F-statistics in parentheses.

Discussion

The following statements briefly summarize the key results of the preceding analyses:

- There is a significant decline—on the order of 50 percent—in labor force participation of end stage renal disease patients associated with the onset of kidney disease.
- This decline in labor force participation is largely a matter of former workers dropping out of the labor force. In very few instances is the treatment of the kidney disease associated with new entry into the labor force.
- Among end stage renal disease patients, poorer health and disability are indeed associated with a lower likelihood of labor force participation. However, it is difficult to rule out labor force participation on the basis of disability alone.
- Overall, although much of the apparent intermodality differences in labor force participation can be attributed to case-mix differences, there is strong evidence that transplant patients are significantly more likely to be labor force participants than in-center patients and the patients on continuous peritoneal dialysis are less likely. Evidence of differences between home and in-center patients, after controlling for case mix, is weak.
- Comparing only home dialysis patients with in-center dialysis patients, home dialysis is associated with a significantly higher probability of labor force participation for white males aged 25-64, but not for females aged 25-64 or (it seems) for other than white males aged 25-64.

These findings have important implications for the end stage renal disease (ESRD) program policy. They suggest that there may have been an overemphasis in the past on the benefits of home dialysis with regard to facilitating labor force participation. Overall, one cannot reject the hypothesis that home dialysis offers no advantage vis-a-vis in-center dialysis. On the other hand, those who promote transplantation on the basis of encouraging labor force participation (or, in other words, rehabilitation) are on somewhat firmer ground. And, based on the small sample here, continuous peritoneal dialysis appears, if anything, to be associated with a lower probability of labor force participation compared to the other three modalities.

These results must be considered limited, however, because they do not go beyond simple exogenous controls for other factors affecting labor force participation. As discussed in the background section, a full behavioral model will need to include measures of expected wages and expected social security benefits. Because these measures are not directly observed for all individuals, they must be constructed by extrapolating from the subsets of patients for whom they are observed.

Yet, despite the limitations of these findings, they do carry much weight in some cases because it is unlikely that the more sophisticated model will accentuate intermodality differences. For example, years of education, which is very significant in all the equations, is a good proxy for expected wage. Thus, the inclusion of expected wage is unlikely to alter the basic findings. At the same time, the inclusion of a measure of expected social security benefits could have a large impact on the apparent difference between transplant patients and the dialysis patients.

A priori, it seems likely that transplant patients would be less likely than dialysis patients to qualify for disability benefits. To be disabled under social security law, an individual must have a physical or mental condition that prevents the performance of "substantial gainful work" and is expected to last (or has lasted) for at least 12 months. "Serious loss of function of the kidneys" is listed as a condition "ordinarily...severe enough to be considered disabling" (Social Security Administration, 1981). Subject to having worked long enough under social security, a disabled individual can begin receiving monthly disability checks in the sixth full month of disabiltiy. The amount of the check is based on the individual's lifetime average earnings. If a transplant patient—because of the existence of the functioning kidney—is less likely to qualify for disability benefits, then their gains from working will be greater. Furthermore, the loss of Medicare benefits to the transplant patient (which occurs 3 years post-transplant) provides an additional incentive for labor force participation. Obviously, the greater labor force participation of transplant patients may be influenced by these factors. However, theory suggests, as discussed in the background section, that those with more total time available are more likely to work, so there is the expectation that some difference will remain.

Future analyses should attempt to directly include financial factors. Other facets of work activity also need consideration. Both the actual rehabilitation services received (described in Evans et al., 1982) and specific adaptations made by employers can be related to work activity. A broader set of work activity measures, such as hours of work and full-time versus part-time work, should be studied. The labor force status of the spouse may directly affect the patient's work decision or may itself be affected by that work decision. This multivariate analysis limited the health measure used to self-reported general health status. Other indicators of disability, functional limitations, and comorbidity need to be considered in future analyses. (Using these more complex measures, however, will often necessitate the loss of some observations due to missing data.) Finally, some of the results from the linear probability model presented here need to be checked against a more robust probit or logit specification, though this is not expected to make a major difference.

Aside from these limitations of technique and model, in closing, some basic limitations in the data used for the analyses deserve mention. First, there is the problem of potential nonrepresentativeness because the 11 participating centers were not selected randomly. Instead, they were chosen purposively to reflect various institutional characteristics as well as to ensure each center's full cooperation in the compelx data collection activities. It is therefore inappropriate to assume that the estimates for this sample can be directly generalized to the entire

ESRD population. This caveat is given even greater strength by noting that 3 of the 11 centers provided 59 percent of the patients in the final sample. On the other hand, the three centers have very different characteristics and thus provide substantial variability in areas important to the study. Ultimately the major objective has not been to make very detailed comparisons across dialysis and transplant centers but rather to estimate quantities for the entire sampling frame. More detailed comparisons across individual centers or centers grouped on some common variable (e.g., for-profit centers versus nonprofit centers) would only be realistic if the centers and patients both had been selected on the basis of probability sampling procedures. In this case, it would have been possible to infer the results from the sample to the entire ESRD patient population.

A second major limitation arises in the attempt to make across modality comparisons. Because individuals are not randomly assigned to treatment modalities, there is a "selection bias." Individuals with the advice of their physician choose the treatment modality on which they expect to fare best. How they would have fared on another treatment modality is unknown. Controlling for case mix by accounting for patient differences in such factors as age, sex, race, and comorbidity is an approximate means for overcoming this problem.

A further limitation of this study derives from the cross-sectional study design, that is, the individual patients were interviewed only once at approximately the same point in time. In contrast, a more expensive longitudinal design, collecting data at several points in time for each individual, would have permitted the analysis of other important questions. Most notably, questions of survival and treatment modality switching over times are impossible or at least difficult to address with a cross-sectional design. Nonetheless, this cross-sectional decision can, with adequate controls for case mix, approximate the goal of case control studies, such as those common in epidemiology (Kurland et al., 1970; MacMahon and Pugh, 1970; Ibrahim and Spitzer, 1979).

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Chapter 14.
Income and poverty

Introduction

By the end of 1981, the end stage renal disease (ESRD) population of the United States was greater than 70,000, including all dialysis and kidney transplant patients, irrespective of their participation in the ESRD program (Chapter 4). Approximately 85 percent of these patients had their medical expenses covered under Medicare. Total Medicare expenditures for the ESRD program were about $1.5 billion, averaging over $20,000 per year per enrollee (Iglehart, 1983; HCFA, 1984). The high cost of the ESRD program has spurred much debate as to its merits. Increasing attention has been given to the outcomes of this treatment. In particular, patient survival has recently received more attention (Weller et al., 1982; Vollmer et al, 1983; Krakauer et al., 1983). Of course, survival is not the only indicator of outcome, the quality of life of patients is also important. Using data from the National Kidney Dialysis and Kidney Transplantation Study, the income distribution and prevalence of poverty among ESRD patients are described in this chapter, and the role of Federal income support in reducing this prevalence is analyzed.

End stage renal disease can have a catastrophic impact on the economic well-being of patients and families, not only because of the direct costs incurred to meet medical expenses but also because of the indirect impact on patients' ability to participate and earn income in the labor force. Previous results from the National Kidney Dialysis and Kidney Transplantation Study have shown a dramatic decline in the labor force participation of individuals accompanying the onset of ESRD (Chapter 13). Federal programs are in place, however, to mitigate these financial impacts both by covering medical expenses (via Medicare) and by providing income support (via social security disability or retirement, and/or Supplemental Security Income). This chapter focuses on the latter issue, showing both the current income levels of ESRD patients and the share of this income derived from these two Federal programs.

Methods

Patients

The analysis that follows is based on the total patient sample (N=859) for the National Kidney Dialysis and Kidney Transplantation Study (NKDKTS). Patients are once again stratified according to treatment modality, the objective being to detect differences by modality. Patients who have experienced a failed transplant have not been examined apart from their current treatment modality.

Income and poverty measures

The income measures reported here are derived from two series of questions in the Patient Interview Schedule for the NKDKTS. The first series asked patients to estimate and report 1981 labor earnings (before tax) for all family members. The second series of questions involved a checklist of recent monthly benefits received under a variety of Federal, State, and employer income maintenance programs. Estimates from this second series were annualized and added to their 1981 family labor income. Because of the phrasing of these questions and the timing of the interviews (they occurred between October 1981 and April 1982), this sum may slightly overestimate the income of some of these households.

Other caveats are in order. Responses to questions about income may well suffer from the usual problems of reliability and validity including outright refusal to report. The figures presented here represent an attempt to use all the pertinent information collected from the NKDKTS. Great care has gone into making imputations that would retain incomplete observations for analysis without compromising or biasing substantive conclusions. These imputations are described in Appendix 14-A. In the end, 120 of the 859 patients (i.e., 14 percent) were excluded because of missing data (or refusal to report this information).

To estimate the number of patients below the poverty line, a measure of the poverty status of each patient was developed. The U.S. Bureau of the Census (1983a) publishes a matrix of poverty thresholds varying by family size, family composition (number of children under age 18), and the age of the householder. Using these thresholds and the data collected in the study on these variables, the relevant poverty threshold (in 1981) for each patient was determined. Patients were designated as being in poverty if their family income fell below that threshold.

Results

Table 14-1 shows the percent of patients by treatment modality receiving social security benefits (SSB), either disability or retirement, and/or Supplemental Security Income (SSI). Clearly, a substantial proportion of patients are receiving Federal support. Over 75 percent of in-center hemodialysis patients receive federal income support, as do 46 percent of transplant patients. Extrapolating to the entire end stage renal disease (ESRD) population from these four estimates suggests that approximately two-thirds of ESRD patients receive Federal income support.[1]

The percent distribution of income, including family earnings and annualized benefits from social security and

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[1] All extrapolations to the ESRD population made in this chapter refer to the unadjusted sample estimates by modality and to the ESRD population modality proportions listed in Chapter 4. No adjustments are made for the age-sex-race-region differences between the sample and the population. We believe that the minor differences that do exist are probably of small consequence for the findings reported here. We refrain, however, from presenting the population extrapolations in the tables, preferring to do so only in the text and in approximate terms.

Table 14-1

Percent of sample receiving income support through Federal programs, by treatment modality and type of support

Type of support	Treatment modality In-center hemodialysis	Transplant	Home hemodialysis	CPD
Number in sample	325	132	273	79
		Percent		
Social security benefits only (disability or retirement)	59.1	41.0	50.6	64.6
Supplemental Security Income only	8.6	3.8	6.7	2.5
Both social security benefits and Supplemental Security Income	8.9	.7	2.5	0.0
Total percent receiving Federal support	76.6	45.5	59.8	67.1

NOTE: CPD is continuous peritoneal dialysis.

Table 14-2

Percent distribution of patients with end stage renal disease, by treatment modality and 1981 family income compared with all U.S. households

Income	All U.S. households[1]	Treatment modality In-center hemodialysis	Transplant	Home hemodialysis	CPD
Total respondents	—	292	125	252	70
Total nonrespondents	—	55	19	35	11
			Percent distribution		
$0-$2,499	2.9	5.8	4.8	3.2	1.4
$2,500-$4,999	7.6	24.7	10.4	11.9	12.9
$5,000-$7,499	7.8	22.9	7.2	10.7	8.6
$7,500-$9,999	7.1	8.2	5.6	7.1	7.1
$10,000-$14,999	14.4	9.3	14.4	17.5	18.6
$15,000-$19,999	12.3	10.3	11.2	11.9	11.4
$20,000-$24,999	11.4	5.5	10.4	7.1	10.0
$25,000-$29,999	9.7	4.8	10.4	7.5	4.3
$30,000-$39,999	13.1	4.5	11.2	9.9	12.9
$40,000-$74,999	12.0	3.4	12.0	10.7	12.9
$75,000 or more	1.7	.7	2.4	2.4	0.0
Percent below poverty line	—	41.7	23.2	21.4	15.7

[1] The number of U.S. households in 1981 was 83,527,000. This percent distribution is from Table 3 in the U.S. Bureau of the Census, *Current Population Reports*, Series P-60, No. 137, Money Income of Households, Families, and Persons in the United States, 1981, Washington, U.S. Government Printing Office, 1983.

NOTES: CPD is continuous peritoneal dialysis. This aggregate income measure includes any 1981 labor earnings (before tax) of all household members plus annualized imputations of any benefits (e.g., social security, pension) they are currently receiving. Other income from assets (dividends, interest, etc.) is not included in the sample estimates, but it is included in the U.S. household estimates.

other programs is shown in Table 14-2. Other nonlabor income, such as interest income and dividends, is excluded from this table. For example, it is shown in Table 14-2 that 5.8 percent of in-center patients reported incomes of less than $2,500 in 1981. And 41.7 percent of in-center patients, who represent roughly two-thirds of all ESRD patients, had family incomes below the poverty line. The last column in Table 14-2 shows the 1981 percent distribution for the U.S. population, in order to provide an outside standard for comparison. For example, 18.3 percent of all U.S. households had annual incomes below $7,500, and over 50 percent of in-center patient households did. Clearly, incomes of the ESRD population are substantially below those of the general U.S. population. Overall, using the approximate percent of the four modalities cited earlier, nearly one-third of all ESRD patients may be living in poverty.

The relationship between poverty status and type of income is shown in Table 14-3. For example, 67.9 percent of in-center hemodialysis patient households would fall below the poverty line on the basis of family labor income alone. Receipt of Federal income support lowers the percent in poverty to 53.8 percent, and receipt of State benefits and employer-related benefits lowers the percent to 41.7. Finally, the addition of other income, such as interest, dividends, and alimony, reduces the percent in poverty to 34.1. This last row represents the best estimate, though probably a conservative one, of the prevalence of poverty among these patients. For reasons explained in Appendix 14-A, this income measure is totally family labor income plus the larger of total other income or annualized total reported benefits. Nonetheless, when extrapolated to the entire ESRD population, the estimates in the last row in Table 14-3 suggest that nearly 30 percent of ESRD patients live in poverty.

These tables raise two major questions. First, is the comparison with the general population inappropriate? Should not ESRD patients be compared with others having the same age, sex, race, and disability status? Second, are patients below the poverty line because of a lack of government support?

The first question is not easy to address because of the lack of published data on U.S. poverty by such detailed characteristics. A limited comparison, comparing poverty rates for more specific groupings, yet not as disaggregated as one would like, is made in Table 14-4. For example, among white persons with a head of household aged 55-64, 6.0 percent of all U.S. families had incomes below the poverty line in 1981. For the comparable in-center hemodialysis patients in this sample, the percent below the poverty line was 19.6 percent. With few exceptions, the proportion of ESRD patients in families below the poverty line greatly exceeds the comparable proportion in the general U.S. population (Table 14-4). This is especially true for in-center hemodialysis patients, the most prevalent patient group. Thus, the greater extent of poverty among ESRD patients does not appear to be simply the result of the age-race composition of the ESRD population.

The second question mentioned above concerns the actual situation of those with incomes below poverty relative to Federal income support. The large majority of these patients do receive benefits from the Federal Government (Table 14-5). Nonetheless, the reported benefits are not sufficient to put them above the poverty line. For those receiving social security benefits (SSB) or Supplemental Security Income (SSI), the total amount received averages between 48 and 59 percent of their respective poverty thresholds.

These findings suggest that the incidence of poverty among ESRD patients is related more to the paucity of benefits than to eligibility for them. Indeed, a detailed examination of the 20 questionnaires of those in poverty but not receiving benefits suggested that seven had applied for SSB and may have been awaiting a decision; two were farmers; one was a student; and four or five others were receiving benefits from other programs. These examples reinforce the view that eligibility is not the major issue. After all, any U.S. citizen who is poor enough is entitled to some level of SSI benefits. Interestingly, only 38 percent of in-center hemodialysis patients in poverty who receive Federal income support also receive SSI benefits. The analogous percent for the

Table 14-3

Percent of patients with end stage renal disease below poverty line, by income measure and treatment modality

	Treatment modality			
Income measure	In-center hemodialysis	Transplant	Home hemodialysis	CPD
	Percent			
Family labor income	67.9	35.7	46.5	47.9
Family labor income plus social security benefits or Supplemental Security Income	53.8	28.0	28.1	32.5
Family labor income plus all other benefits	41.7	23.2	21.4	15.7
Family labor income plus all other income[1]	34.1	16.5	14.0	11.6

[1] As explained in Appendix 14-A, this measure was not constructed for the entire sample, only for those below or near poverty.

NOTE: CPD is continuous peritoneal dialysis.

Table 14-4

Percent of all U.S. families and of patients with end stage renal disease with 1981 incomes below the poverty line, by race, age, and treatment modality

Race and age	All U.S. families 1981[1]	National Kidney Dialysis and Kidney Transplantation Study patients: In-center hemodialysis	Transplant	Home hemodialysis	CPD
		Percent below poverty line			
White					
18-24 years	18.2	42.9 (7)	16.7 (18)	12.5 (8)	—
25-44 years	10.1	22.2 (27)	14.1 (64)	12.8 (86)	0.0 (19)
45-54 years	6.5	11.8 (34)	5.3 (18)	6.4 (47)	8.3 (12)
55-64 years	6.0	19.6 (46)	28.6 (7)	16.1 (56)	6.7 (15)
65 years or over	7.2	13.2 (38)	—	14.3 (21)	44.4 (9)
Black					
18-24 years	50.0	—	—	—	—
25-44 years	28.0	42.2 (45)	11.1 (9)	16.7 (12)	
45-54 years	23.0	51.4 (35)	—	—	—
55-64 years	20.1	75.0 (24)	—	14.3 (7)	—
65 years or over	26.4	54.5 (22)	—	—	—

[1] The number of U.S. families in 1981 was 61,019,000. These estimates are from Table 5, U.S. Bureau of the Census (1983a).

NOTES: CPD is continuous peritoneal dialysis. The number of sample members in each cell is shown in parenthesis. '—' denotes less than 5 observations in cell.

Table 14-5

Percent of patients with end stage renal disease below the poverty line receiving Federal income support, by treatment modality

Type of support	Treatment modality: In-center hemodialysis	Transplant	Home hemodialysis	CPD
Number below poverty line	99	21	36	8
Percent receiving social security benefits and/or Supplemental Security Income	88.1	81.0	86.1	100.0
For those receiving benefits, benefit amount as percent of poverty line	52.3	48.0	54.9	58.7

NOTE: CPD is continuous peritoneal dialysis.

other modalities are 17.7, 22.6, and 12.5 for transplant, home hemodialysis, and CPD patients, respectively. This raises the possibility that some inroads could be made by encouraging ESRD patients to seek SSI benefits.

Conclusion

From these tables, three major conclusions can be drawn: nearly two-thirds of the end stage renal disease (ESRD) population is receiving Federal income support either through the social security program or Supplemental Security Income (SSI); yet, a significant proportion—nearly one-third—of ESRD patients are living in households with incomes below the poverty line; and although income transfers to households through the Federal programs appear to raise many households above the poverty line, the large majority of ESRD patients in poor families receive Federal benefits that are insufficient to place them above the poverty threshold.

The second conclusion can be amplified to emphasize that the apparent high prevalence of poverty among ESRD patients is not simply a compositional effect that resulted from a skewed demographic distribution. Instead, the prevalence of poverty is much higher than that in the general population for specific age-race groups. Thus, poverty appears to be related to the disability associated with ESRD. This chapter, however, does not address whether ESRD patients have lower incomes than other disabled individuals. The third conclusion suggests that the problem of poverty in the disabled population is largely a matter of the level of benefits and not just eligibility for them.

This analysis has not directly considered the relationship between work and poverty. Previous analyses in this study show that although only about 30 percent of ESRD patients in this sample are participating in the labor force, health status indicators, such as activity limitations, are often poor predictors of this labor force participation (Chapter 13). No doubt the Social Security Disability Program, in particular, discourages some of the able from working. The ESRD patient often faces the difficult choice of working and receiving an income only slightly greater than the poverty line or not working and drawing an income below the poverty line. This analysis does not suggest how often this is the case.

These results suggest a significant need for assistance on the part of many ESRD patients living below the poverty line. This problem of the paucity of benefits may not be unique to the ESRD population, but may apply to other groups of disabled individuals as well. There remains the interesting possibility that the SSI program could be used further to alleviate some of the problem. Although not addressed here, it is quite possible that the burden of poverty on the families of ESRD patients may be greater because of the often substantial out-of-pocket medical expenses.

Clearly, important unanswered questions remain to be examined. How do these ESRD patients meet their medical expenses? To what extent does the social security disability program truly discourage return to work? Further analyses of data from the National Kidney Dialysis and Kidney Transplantation Study can provide at least some limited answers to these types of questions.

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Appendix 14-A.
Definition and construction of income variables

The income measures used in this analysis are based on a series of questions from the Patient Interview Schedule of the National Kidney Dialysis and Kidney Transplantation Study. A variety of assumptions and imputations were made in order to overcome problems associated with nonresponse and question ambiguity. The purpose of this appendix is to describe briefly the steps taken in developing the measures.

Questions 257-260 asked the respondents to estimate expected 1981 earnings from work for themselves, their spouses, and other family members. Essentially, these earnings estimates are totalled to yield 1981 Family Labor Income. Unfortunately, some problems arise because of missing values. Sample members were considered nonrespondents and were excluded from the analysis for the following reasons:

- If they did not report their own 1981 labor income (Question 257).
- If they were married but failed to report their spouse's income.
- If they indicated that other family members contributed to household earnings but failed to supply the amount.

In Question 226, respondents were asked if they currently received any of 12 types of Government or employment-related benefits and the monthly amount received for each type. As mentioned in the text, there is a timing problem because this question asks about current benefits; the labor income questions were for 1981; and the interview occurred between September 1981 and May 1982. We chose to extrapolate monthly benefits to an annual basis and to add this to the 1981 labor income. This may lead to an overstatement of 1981 family income in some instances. For those who said they received a particular benefit, such as Social Security retirement, but who did not report an amount, the average amount for those receiving that benefit in the same modality (e.g., among transplants) was assumed.

If a respondent was missing information for both social security benefits and Supplemental Security Income, they were excluded from the income analyses. Otherwise, they remained in the analysis, and any other nonresponses were given a value of zero. Thus, the nonlabor benefits are best thought of as reported benefits.

Total family income is defined as the sum of reported annual benefits and family labor income. Other income, such as dividends and interest, is generally excluded. Question 261 was aimed at gathering this information, but a study of responses revealed the data to be of poor quality. The basic problem was, however, that occasionally respondents gave total family income in 1981 rather than the total family nonlabor income in 1981. It was decided that the responses generally were not usable. However, it was possible to use this variable for the poor, who generally did not have any labor income. In the last row of Table 14-3 and in Table 14-4 the larger of this income measure or total reported benefits is used.

Finally, respondents were given the option of answering the income questions in an inclusive, catch-all form—Question 262. This question asked respondents to place total 1981 family income into one of 14 income categories. Those few individuals who responded only to this question were assigned the midpoint of the relevant range. (A slight inconsistency was introduced because this question includes interest and dividend income.)

The objective of these imputations and assumptions was to preserve as much of the useful sample information as possible. In the end, only 14 percent of the 859 respondents were excluded from the analyses.

Costs

Chapter 15.
Costs of treatment

Introduction

Eggers (1984) has summarized well both the policy issues related to the cost of treatment for end stage renal disease (ESRD) and our knowledge of the determinants of cost differences among patients. The Federal ESRD program continues to be a focal point because ESRD beneficiaries account for 3.7 percent of the total Medicare expenditures even though they comprise only one-quarter of 1 percent of all beneficiaries. Furthermore, their share of expenditures will grow because total program expenditures grow on the order of 30 percent per annum, which is faster than the growth in Medicare expenditures overall.

Eggers shows that enrollment growth is the major determinant of the growth in total program costs. However, because enrollment is not easily manipulable through policy changes, greater attention has been given to possible methods of reducing per enrollee costs.[1] Reimbursement per enrollee rose from $14,300 in 1974 to $23,000 in 1981 (in nominal terms). Some analysts (for example, Lowrie and Hampers, 1981) have made the point that, after adjustment for inflation, real costs per enrollee are virtually unchanged over the period 1974 to 1979. On the one hand, this suggests that the Government's attempts to reduce ESRD treatment costs have been unsuccessful. On the other hand, it is remarkable that real medical costs for any particular treatment were constant over this period of rapidly rising real medical (and especially hospital) costs per capita.

The discussion of possible methods for reducing costs has largely focused on the costliness of alternative modalities—home hemodialysis, in-center hemodialysis, transplantation, and various forms of peritoneal dialysis. The Government has attempted to encourage home hemodialysis and kidney transplantation, which have always been viewed as less costly. Putting aside the question of whether these modalities are truly less costly, the effort to promote them has failed, as evidenced by the declining share of home hemodialysis patients and the slow growth in transplants (Health Care Financing Administration, 1983).

Eggers (1984) also presents evidence that in 1979 the average home patient cost Medicare $18,700 and the average in-center patient cost $23,600. Yet, even this cost saving could be apparent rather than real if there are cross-subsidies from in-center patients to home patients, as has been suggested by Held and Pauly (1979). Eggers (1983) shows that transplantation may be more cost-effective from Medicare's point of view than is dialysis: The high cost in the first year because of transplant operation (approximately $30,000 in 1978) is offset by the low costs in later years (which fall to zero for Medicare after the third year). Whether home hemodialysis and transplantation are less costly from society's point of view remains an open question.

Eggers (1984) also examines differences in Medicare reimbursement by demographic and medical characteristics for dialysis and transplant patients. Generally speaking, the differences by age, sex, or race within modality are small. Also, primary cause of renal failure is not a major determinant of average reimbursement level. Other studies have focused on the impact of case mix on costs in different types of facilities. The motivation for these studies was that uniform reimbursement rates, by ignoring actual costs, discriminate against certain types of facilities that happen to treat a more severely ill group of patients. Certainly, sicker patients would require more care on the average. Plough et al. (1984) provide medical evidence that hospital-based facilities in Michigan treat more severely ill cases on the average than freestanding facilities do. The problem is that the demographic and health measures used as case-mix indicators not only are poor predictors of health outcomes but also may be only weakly related to treatment costs.

A further, more subtle complication is that costs are not simply determined by medical differences among patients, they, for example, reflect provider choices about location, quality of accommodations, etc. It has been argued (Bovbjerg, Held, and Pauly, 1982) that in competitive market areas, there will be a tendency for costs to approach the reimbursement rate as dialysis providers compete for patients. Held and Pauly (1983) provide empirical evidence supporting this. Thus, using cost-finding exercises to set reimbursement rates may prove fruitless.

One limitation of many of these previous studies is that they lacked the detailed data on individual patients needed to examine the case-mix issue in a multivariate framework. Data from the National Kidney Dialysis and Transplantation Study (NKDKTS) provide an opportunity for overcoming this limitation. This report describes an attempt, taking advantage of the unique sample and survey of the NKDKTS, to examine the impact of modality versus case mix as determinants of differences in costs to Medicare of patients on differing modalities. The main issue addressed is: Are the apparent cost advantages of home hemodialysis and transplantation, as compared with in-center dialysis, the result of differences in case mix?

Data and methods

The data for this analysis come from the patient survey of the National Kidney Dialysis and Kidney Transplantation Study (NKDKTS) that was linked to patient reimbursement records from the Medicare Statistical System (MSS). The former has been described in other sections of this report. The latter has been described by Eggers (1984). Briefly, a record of all claims made by end stage renal disease (ESRD) beneficiaries is maintained in the MSS. This includes both claims under hospital insurance (Part A) and medical insurance (Part B). With the permission of survey patients, an attempt was made to obtain all claims in the MSS ever made on their behalf. This analysis focuses on the following three types of claims:

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[1] Successful transplantation has the potential for lowering costs by reducing enrollment because Medicare eligibility expires 3 years post-transplant if the graft is still functioning and if the patient is not disabled.

- Inpatient and skilled nursing facility billings (HCFA Form 1453).
- Outpatient billings by providers (HCFA Form 1483).
- Physician and supplier billings (HCFA Form 1490).

(Facsimiles of these forms are shown in Appendixes 15-A, 15-B, and 15-C.) For each of these three separate types of claims, the records were summarized into annual reimbursement totals for each patient for each year since joining the ESRD program. The analysis here, however, is restricted to their summaries for 1981, the year of the survey.

As shown in Table 15-1, a number of factors reduce the number of sample observations available for analysis. First, of the 859 original observations, 33 did not provide health insurance claim numbers, which are needed to obtain a match in the MSS system. For another 110 patients, no match was found in the MSS system. This could be because of error in the health insurance claim numbers: The patients' health insurance claim numbers may differ from their own social security numbers (which were requested in the survey). Third, although some matching information was obtained, there were no Part A or Part B claims for 62 of the patients. The analysis was restricted to those with at least 1 full year on their current modality, and it was required further that 1981 had to be a full year on the modality. Finally, 42 transplant patients with a graft functioning for more than 36 months were excluded because they are likely to have lost Medicare coverage. This results in a final sample size of at most 438 observations available for analysis. However, missing data on variables sometimes reduces the number of observations available for analysis to even less than this for particular analyses.

The limitations of this analysis should be apparent. The sample of patients and centers is not nationally representative. Any biases in the selection or matching process with the MSS system are unknown. Considerable effort has gone into developing the cost measures used in these analyses. Although the quality and reasonableness of the available claims appear good, there remains some uncertainty as to whether all claims have been captured by the system. There is no easy way to check this. The fundamental problem is that if no claim of a given type is reported in 1981, can it be assumed that no claims were made—or is the information missing? The assumption made is that if there are previous claims in the system, then use in 1981 was zero. But if there are no claims of that type, then the data are assumed to be missing. This raises severe problems for inpatient utilization which is, by its very nature, sporadic, as compared with the outpatient use of ESRD patients. In general, there may be some systematic bias downward in the average cost estimates reported here. However, given that the analysis focuses on differences among modalities and because the majority of patients appear to have claims, the substantive results are not likely to be affected by these data problems.

Table 15-1

Number and percent distribution of original sample and working sample with exclusion criteria for working sample

Sample and exclusion criterion	Number of observations	Percent distribution
Original sample	859	100.0
Home hemodialysis	287	33.4
In-center hemodialysis	347	40.4
Continuous peritoneal dialysis	81	9.4
Transplant	144	16.8
Minus 33 respondents not providing health insurance claim numbers	826	—
Minus 110 with no claims found in the Medicare statistical system	716	—
Minus 62 with either Part A or Part B missing	[1]654	—
Minus 134 with less than 1 year on modality	520	—
Minus 40 without full year on modality in 1981	480	—
Minus 42 with more than 3 years post-transplant	438	—
Working sample	438	100.0
Home hemodialysis	182	41.6
In-center hemodialysis	195	44.6
Continuous peritoneal dialysis	22	5.0
Transplant	39	8.9

[1] This represents the sample with some Part A and Part B data.

Two types of analyses are performed. First, there are cross-modality descriptive analyses for each of the three types of Medicare expenditures. These analyses compare the three ESRD dialysis modalities—home hemodialysis, in-center hemodialysis, and continuous peritoneal dialysis (CPD)—and transplantation. Second, there are regression analyses of differences among the dialysis modalities for each of the three types of expenditures. Transplant patients are left out of the regressions because of the small number of observations and because of the very different nature of their treatment.

The variables used in the regression analyses and their means are given in Table 15-2. Note that the dependent variables are based on different sample sizes because of sample exclusions and restrictions and because of missing values. The means for the independent variables are for the largest sample used in the regressions. Most of the variables are self-explanatory. The subsample of 389 observations is not unlike the original sample for some of the key independent variables. The original sample had a mean age of 47.6 years, 55.4 percent males, 72.6 percent white, and a mean education of 12.1 years

Table 15-2
Variable definitions and means for regression analyses

Variable	Definition	Mean[1]
Dependent variables		
Physician and supplier reimbursement	Total 1981 payments per patient by Medicare to physicians and suppliers under Part B	$4,039
Outpatient provider reimbursement	Total 1981 payments per patient by Medicare to facilities, laboratories, etc.	$10,402
Total outpatient reimbursement	Sum of the above two variables	$18,678
Total inpatient reimbursement	Total 1981 inpatient payments per patient by Medicare under Part A	$4,683
Inpatient admissions	Number of admissions per patient in 1981	1.96
Inpatient days	Total days of inpatient care per patient in 1981	11.55
Treatment modality		
In-center	1 if on in-center dialysis 0 otherwise	.487
Home	1 if on home dialysis 0 if otherwise	.458
CPD	1 if on continuous peritoneal dialysis 0 otherwise	.057
Case-mix measures		
Diabetes	1 if diabetes was case of renal failure 0 otherwise	.067
Male	1 if male 0 otherwise	.578
Age	Patient age in years	49.4
White	1 if Caucasian 0 otherwise	.715
Time on therapy	Months on current therapy	51.4
Comorbidity	Number of comorbid conditions at time of survey	1.23
Education	Number of years of formal schooling	12.1
Other control variables		
Center i	Center dummies, i 1 , 11. 1 if patient from Center i 0 otherwise	(.30,.20, .07,.02, .04,.01, .15,.02, .08,.05, .07)

[1] Mean value of independent variables are from sample size of 389 in the Part B regressions in Table 15-5. Means of dependent variables are for the corresponding regression samples in Tables 15-5 and 15-7.

(Chapter 5). The center dummies at the bottom of the page reflect the center where the patient was treated. In the context of regression analysis, these variables would reflect not only effects related to the center itself but also regional and market effects related to the particular geographic locales of the centers.

A final note on terminology—the terms "cost" and "Medicare reimbursement" are used interchangeably. It should always be remembered that this use of "costs" does not mean that these expenditures represent actual resource costs to society. Cross-subsidies, inefficiencies, and other distortions may lead to differences between these measures and true resource costs. The term "charges" represents the amount listed by the hospital, physician, or supplier as the total charge for the service. Medicare reimbursements are less than this because of patient deductibles and coinsurance as well as Medicare cost reimbursement methods and fee screens. In theory, the patients bear the difference between reimbursement (or costs to Medicare) and charges.

Results

Presented in Table 15-3 is descriptive information on Medicare payments to physicians and suppliers on behalf of beneficiaries on each of the four treatment modalities. The following patterns are as expected:

- Home hemodialysis and patients on continuous peritoneal dialysis (CPD) have larger mean payments to physicians and suppliers than in-center or transplant patients do. These payments represent reimbursements for their home medical supplies associated with dialysis. Over 50 percent of the payments for home patients go to medical suppliers.
- The majority of payments for in-center patients are for medical consultation and other physician payment under the alternate method and for physician services related to surgery and anesthesia.
- The bulk of expenditures for transplants are, as the distribution by place of service shows, related to inpatient services; and as type of service shows, these are for physician services related to hospitalization.
- For all modalities reimbursement runs at about 80 percent of total charges, as is expected under the medical insurance part of Medicare. Clearly, if home and CPD patients actually pay these amounts, there is a significant out-of-pocket burden. Those with no charges are presumably having their suppliers and any physician treatment handled through a dialysis facility.

Medicare reimbursement and charges for the services of other outpatient providers by the four treatment modalities are shown in Table 15-4. These are primarily payments to dialysis facilities and to laboratories. Again, the pattern is as would be expected. In-center patients, by virtue of Medicare payments to their centers, have the highest reimbursement level—nearly $12,000 per patient in 1981. Reimbursement levels for home hemodialysis and CPD patients are somewhat lower. Many of the home patients are managed by the facility for a flat reimbursement rate, rather than being reimbursed for actual expenses. Billings for transplant

Table 15-3

1981 mean annual expenditures for physicians and suppliers, by treatment modality, and percent, distribution within modality by type of expenditure

Item	Treatment modality Home hemodialysis	In-center hemodialysis	CPD	Transplant
Number of observations	182	195	22	39
Medicare reimbursement	$5,101	$2,751	$6,119	$810
Standard deviation	5,082	2,498	8,060	1,006
Charges	$6,391	$3,431	$7,649	$984
Percent with no charges	6.5	9.2	13.6	15.4
	Percent distribution			
Place of service				
Outpatient	17.2	53.6	2.4	18.3
Home	47.3	0.5	36.5	1.8
Inpatient	10.8	38.1	8.6	60.3
Other	24.7	7.9	42.5	15.7
Type of service				
Medical consultation	13.0	36.5	11.2	26.7
Surgery and anesthesia	6.5	22.0	4.6	23.8
Radiology	3.5	7.5	1.4	44.2
Alternate method	15.2	31.6	7.3	0.0
Other	61.8	2.4	75.6	5.3
Type of supplier				
Primary care				
Physician	4.6	9.5	2.4	2.8
Surgeon	4.4	30.1	2.4	22.6
Internal medicine	15.4	15.4	6.3	7.0
Hospital-based physician	4.0	5.6	3.7	32.6
Nephrologist	9.9	37.4	9.2	18.7
Other physician	9.3	0.9	6.2	2.5
Medical supplier	51.8	0.6	75.6	1.2
Independent laboratory	0.6	0.4	0.2	12.5

NOTE: CPD = continuous peritoneal dialysis.

Table 15-4

1981 mean annual expenditures for outpatient providers, by treatment modality and percent distribution within modality, by type of service

Item	Treatment modality Home hemodialysis	In-center hemodialysis	CPD	Transplant
Number of observations	167	180	21	27
Medicare reimbursement	$8,820	$11,828	$10,376	$902
Standard deviation	5,962	6,974	6,850	1,103
Charges	$10,823	$15,525	$12,995	$1,248
Percent with no charges	3.0	0.0	0.0	0.0
	Percent distribution			
Type of service				
Laboratory	3.9	4.7	5.2	61.8
Radiology	0.8	0.6	0.4	9.1
Pharmacy	0.1	1.1	0.0	0.9
Other[1]	95.3	93.6	94.4	28.1

[1] Represents payments to dialysis facilities for the most part.

NOTE: CPD is continuous peritoneal dialysis.

patients under this part of Medicare largely reflect laboratory charges. Again, the difference between charges and reimbursement, reflecting the patient coinsurance provisions of medical insurance, suggest that dialysis patients may face considerable medical expense burden. Note that the variation in reimbursement relative to the mean is less in Table 15-4 than in Table 15-3. Payments to dialysis facilities are less variable than the use of physician services is.

Regression results from an analysis of differences in these outpatient expenditures by modality, case mix, and center are presented in Table 15-5. (As mentioned above, transplant patients were not included because of the small number of cases.) Because some of the differences between physician and supplier billings and outpatient provider billings may simply reflect different ways of paying for the same service, it is somewhat misleading to treat them separately. For this reason the last two columns of the table show them combined into one total. The first column shows that the differences among the three dialysis modalities in physician and supplier billings are not significantly affected by patient case mix. CPD and home hemodialysis Medicare reimbursement amounts are also significantly higher ($3,337 and $2,672, respectively, relative to the excluded category—in-center dialysis). The second column suggests that the mean differences in outpatient provider billings are also insensitive to patient case-mix, with the

Table 15-5
Outpatient reimbursement: Regression results

	Dependent variable			
Independent variables	Physician and supplier reimbursement	Outpatient provider reimbursement	All outpatient reimbursement	All outpatient reimbursement
Constant (in-center)	1,855 (1.9)	12,711 (8.2)	14,491 (9.3)	15,233 (9.6)
Home	***2,672 (5.3)	***-3,608 (4.5)	-758 (1.0)	***-2,509 (4.0)
Continuous peritoneal dialysis	***3,337 (3.4)	-1,776 (1.1)	2,523 (1.6)	304 (.2)
Diabetes	1,646 (1.9)	*-2,868 (2.0)	-1,197 (.9)	99 (.1)
Male	764 (1.7)	133 (.2)	594 (.8)	-96 (.2)
Age	19 (1.2)	-22 (.9)	10 (.4)	18 (.9)
White	-615 (1.9)	1,307 (1.6)	329 (.4)	275 (.4)
Time on therapy	-5 (.9)	-.6 (.5)	-11 (1.1)	-1 (.2)
Comorbidity	—	—	—	214 (1.2)
Education	—	—	—	73 (.9)
Center 1	—	—	—	—
Center 2	—	—	—	***-5,222
Center 3	—	—	—	**2,773
Center 4	—	—	—	-2,921
Center 5	—	—	—	-1,175
Center 6	—	—	—	**7,109
Center 7	—	—	—	***-10,764
Center 8	—	—	—	193
Center 9	—	—	—	*2,097
Center 10	—	—	—	116
Center 11	—	—	—	***3,982
Adjusted *R*-Squared	***.089	***.050.0 04	***.456	
Number of observations	389	358	328	328

*Significant at .05 level.
**Significant at .01 level.
***Significant at .001 level.
NOTE: t-statistics in parentheses.

surprising exception that diabetic patients appear to have lower expenditures. The two types of outpatient billings summed are the dependent variable in the third column, with the result of almost no differential among the three modalities. Furthermore, none of the case-mix measures has a significant effect. The fourth column shows that the results on modality are very sensitive to the inclusion of dummy variables measuring center effects. After controlling for these center effects, it appears that outpatient costs for home hemodialysis are significantly less than for in-center hemodialysis. There is no significant difference apparent from the few CPD patients included in the sample. Importantly, none of the case-mix measures has any impact.

As has been explained elsewhere (Chapter 4), the purposive nature of this sample leads to a correlation between modality and center. As shown in the fourth column, once this is controlled for, there are significant center effects on Medicare reimbursements that are unrelated to either modality or case mix. The center effects are expressed relative to an excluded dummy—Center i. Some centers receive significantly greater reimbursement per patient and others, significantly less.

Of the four regressions in Table 15-5, the fourth column provides the best estimates of modality and case-mix effects. (The dependent variables in the first two regressions are only partial measures of out-patient costs and the third column is misspecified by ignoring center effects.) Thus, it appears that case-mix has little impact on outpatient reimbursement for dialysis patients. The common finding that home hemodialysis costs Medicare less is not affected by the inclusion of case-mix measures.

Presented in Table 15-6 is descriptive information on the use of and expenditures for inpatient services by treatment modality. It should be remembered in the case of transplants that these are people who have been on this modality for at least a year, so that the transplant operation itself is not included. As a group, the differences across modalities are not significant. Home patients tend to have slightly fewer payments by Medicare on their behalf than in-center patients. Again, there may be a data problem for the in-patient expenditures because the percent with no charges during 1981 is a measure open to some doubt. The differences in expenses more or less mirror the differences in total days of care, which reflect the differences in admissions. Evidently, length of stay per admission does not vary greatly. This is similar to the analysis of self-reported hospitalization performed in the National Kidney Dialysis and Kidney Transplantation Study (NKDKTS) for beneficiaries (Chapter 9). This sample averages about two admissions per year. The composition of expenditures does not differ greatly among the dialysis modalities, although transplant patients are more likely to undergo follow-up intensive care rather than further surgery and anesthesia. The percent of their expenses on laboratories is also much greater.

Shown in Table 15-7 are regression estimates of differences in inpatient use and reimbursement among the dialysis patients. For the three measures used, there is little evidence of differences among the modalities, though if anything, the few patients on continuous peritoneal dialysis in the sample appear to have fewer hospitalizations. In general, the case-mix measures are not significant, with a few notable exceptions. Diabetes, as the underlying cause of renal failure, is significantly related to hospital expenses. Inpatient costs for diabetic patients are $5,310 higher per year, other things being equal. The number of comorbid conditions is also

Table 15-6

1981 mean annual inpatient expenditures and use by treatment modality and percent distribution within modality, by type of expenditure

	Treatment modality			
Item	Home hemodialysis	In-center hemodialysis	CPD	Transplant
Number of observations	90	127	11	20
Medicare reimbursement	$4,472	$4,867	$3,909	$4,051
Standard deviation	6,286	6,440	3,622	4,267
Charges	$6,385	$7,795	$4,669	$6,169
Percent with no charges	5.6	4.7	0.0	0.0
Inpatient admissions	2.04	2.14	1.72	1.95
Inpatient days	10.8	13.6	9.45	13.75
	Percent distribution			
Type of charges				
Accommodation	27.6	24.8	28.8	29.6
Intensive care	7.5	5.4	3.9	9.1
Surgery and anesthesia	11.6	10.3	12.5	6.7
Pharmacy	5.9	7.6	10.9	14.4
Radiology	3.1	3.4	4.1	7.0
Lab	13.6	13.8	11.5	23.2
Other	30.3	34.4	28.0	9.9
Noncovered	0.4	0.4	0.2	0.2

NOTE: CPD is continuous peritoneal dialysis.

Table 15-7

Inpatient use and reimbursement: Regression results

Independent variables	Dependent variable: Inpatient admissions	Inpatient days	Annual reimbursement
Constant (in-center)	***3.16	***22.5	***9,643
	(5.4)	(4.3)	(3.8)
Home	.07	−1.1	−235
	(.3)	(.5)	(.2)
Continuous peritoneal dialysis	−.63	4.5	−2,040
	(1.3)	(1.1)	(1.1)
Diabetes	***.92	***15.2	**5,310
	(2.6)	(4.9)	(3.5)
Male	−.19	.5	210
	(.9)	(.3)	(.2)
Age	−.002	−.08	−31
	(.2)	(1.3)	(1.0)
White	−.002	2.7	817
	(.5)	(1.2)	(.8)
Time on therapy	−.002	−.007	−5
	(.5)	(.3)	(.4)
Comorbidity	*.12	*1.04	*515
	(2.1)	(2.0)	(2.1)
Education	***−.11	***−1.0	
		1	**−397
	(3.6)		(2.9)
Center 1	—	—	—
Center 2	−.13	.9	−1,040
Center 3	.01	.7	−2,339
Center 4	−1.14	−6.0	−3,736
Center 5	−.16	2.9	−1,407
Center 6	.95	−.9	−990
Center 7	−.54	3.6	2,135
Center 8	−.70	3.3	−1,164
Center 9	.49	*8.1	**4,825
Center 10	−.58	−.1	−1,323
Center 11	−.56	−4.1	−2,934
Adjusted R-squared	***.11	***.17	***.13
Number of observations	222	222	222

*Significant at .05 level.
**Significant at .01 level.
***Significant at .001.
NOTE: t-statistics in parentheses.

significantly related to annual reimbursement: Each additional condition increases costs by about $500 per year. These impacts of comorbidity on use are similar to earlier results when self-reported hospitalization for the NKDKTS sample is used (Chapter 9). Interestingly, those with higher education are likely to have fewer inpatient Medicare payments on their behalf, other things being equal. Presumably, this is related to the well-known correlation between health and education, though the mechanism through which this works is unknown. Finally, the center dummies are generally not statistically significant. Despite well-known regional differences in hospital use in the United States, and differences in wages across the country, etc., there are no center effects on inpatient use.

Summary and discussion

The major results from the preceding analyses can be briefly summarized as follows:

- In general, controlling for other factors, most of the case-mix measures are unrelated to either outpatient payments or inpatient payments made on behalf of end stage renal disease (ESRD) beneficiaries in this survey. Only with respect to inpatient use and expenditures do selected health status indicators show an impact.
- Because of their lower outpatient reimbursements, home hemodialysis patients appear to be less costly from Medicare's point of view than either in-center

hemodialysis patients or patients on continuous peritoneal dialysis (CPD). From the few observations available, CPD patients are not significantly less costly than in-center patients.

- Transplant patients with well-functioning grafts are significantly less costly to Medicare than those on dialysis treatment.
- For outpatient payments on behalf of dialysis patients, there are significant differences among centers in the payment levels, controlling for modality and case mix.

The lack of differences by case mix among the dialysis patients suggests that these indicators would not provide a sound basis for a case-mix adjustment for outpatient reimbursement. These results, based on a multivariate analysis, corroborate the findings of a lack of case-mix differences based on bivariate comparisons (Eggers, 1984). Of course, this result is not directly applicable to the question of whether hospital-based facilities have a worse case-mix (and presumably higher costs per patient) than freestanding facilities do. For the most part, the patients in this sample are from freestanding facilities, though some sample members dialyze in hospital settings. However, there are some severely ill patients in the sample.

Mean reimbursement for the home hemodialysis patients in this sample sums to $18,392 in 1981, which can be compared with Eggers' (1984) estimate for home patients of $18,692 in 1979. Mean reimbursement for in-center patients of $19,446 is lower than Eggers' estimate of $23,521 in 1979. This could reflect both a downward bias because of deficiencies in the data and because these patients are a different group than those in his analysis. These patients represent patients stabilized on their therapy and Eggers' aggregate estimates may include those in transition between modalities. These transitions could lead to greater expenditures, for example, if a transplanted kidney fails and the recipient returns to dialysis. The transplant estimates are more comparable to Eggers' figures. The mean cost for transplants of about $4,700 per year is slightly higher than his estimate of $4,074 for transplants with graft functioning in 1979.

The finding that, for outpatient care, home hemodialysis costs Medicare less than in-center hemodialysis is consistent with results of previous investigators. The differential of $2,500 is somewhat less than that reported in Eggers (1984). The possible downward bias caused by data omissions suggests caution in attributing confidence to the magnitude of the differential. Interestingly, for the few CPD patients in the sample, there is no evidence that costs are lower than those for similar in-center patients. This is an important result if it holds up in larger samples. The difference between home hemodialysis and in-center hemodialysis patients, though significant, is well within the range that Held and Pauly (1979) suggest as the magnitude of cross-subsidy from in-center patients to home patients. Thus, one must be wary of attaching too much importance to this result.

The findings that transplants with well-functioning grafts have significantly lower costs corroborates earlier findings and is consistent with what would be expected a priori. It says nothing, however, about the overall cost-effectiveness of transplantation, which is affected by the high cost of transplant itself and the costs of associated graft failures and deaths.

The most surprising finding in these analyses is a substantial impact of center on the cost of dialysis. As suggested earlier, it is unclear to what extent this reflects different efficiencies among the centers, different costs of labor and materials across the centers, or other regional effects. The important point is that these differences have far more explanatory power than modality effects do, and they are more substantial than any differences resulting from case-mix. Indeed, given that there are significant elements of flat-rate reimbursement across centers nationally, it is hard to understand how costs could differ to such a degree. Perhaps some portion of the variation is because of physician and supplier reimbursement, which is known to exhibit substantial variation across geographic areas.

Although not shown explicitly in Table 15-5, some of the largest differences arose in payments to dialysis facilities. This presumably occurs because some centers have been granted higher reimbursement through the exceptions process or because some have the physician fee included in the facility payment. If the latter underlies the differences, then it is variation in physician fees, rather than dialysis payments, that is the source. Under the exceptions process, some centers were allowed reimbursement of over $211 per dialysis session in 1980, as compared with the standard rate of $138 (Health Care Financing Administration, 1982). At 156 treatment sessions per year, this could give rise to a differential of over $11,000 per year. The center dummies may just be capturing these differentials. If so, they do not necessarily imply that similar patients are using vastly different amounts of resources at the centers in the sample. Although the number and length of dialysis sessions probably do not differ much between a typical dialysis patient and a severely ill one, the labor costs of monitoring an ill patient and the extra equipment costs for better backup could be much greater. If the exceptions were granted for higher costs related to a more complex case-mix, then these regressions on a stabilized subsample may not reflect this complexity. Nonetheless, it is important that, controlling for center, no case-mix effects are evident. A nagging question remains: If measurable case-mix matters so little, how can such large differentials be justified on case-mix grounds or on input price differences?

The change in the coefficient on home dialysis outpatient reimbursement with the inclusion of center dummies suggests a substantial correlation between the two. In fact, in the regression sample, 1 of the 11 centers represents nearly one-third of the observations in the analysis. This center is known to have the highest percent of home hemodialysis patients. Because the geographic distribution of home patients across the United States is far from uniform (a few States have the bulk of the patients), comparing national averages for the modalities could be similarly misleading.

Some of this analysis and discussion may be moot if in-center hemodialysis continues to be the dialysis modality of choice by a vast margin and if CPD continues to grow among home patients (Health Care Financing Administration, 1983). Among this sample of more or less stabilized patients, the finding of no case-mix differences would not surprise some observers. The bulk of outpatient expenditures are related to the fixed number of dialysis treatments, implying a fixed cost within center. Other differences that arise would be caused by occasional illnesses that require physician treatment or hospital care. Such outpatient use is small compared with total provider and physician payments; and inpatient use is related to health status though not to modality or other case-mix indicators. The findings that home hemodialysis costs Medicare less, once case mix is controlled, will meet with approval among the supporters of home hemodialysis. Skeptics will argue that costs to Medicare are not indicative of true resource costs.

Finally, despite Medicare coverage, the remaining burden on the patients themselves is not inconsequential, averaging $3,000-$4,000 per year. Given that nearly two-thirds of the ESRD population is already receiving Federal income support because of low incomes (Chapter 14), one wonders how they cope with such large medical expenses.

Acknowledgment

We would also like to thank Dr. Phillip J. Held and his colleagues at the Urban Institute for their computational assistance. They carried out the difficult task of retrieving records from the Medicare Statistical System for the observations in our sample and generously provided expert advice on the manipulation of these records.

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Appendix 15-A
Inpatient and skilled nursing facility billing

Form Approved
OMB No. 0938-0010

INPATIENT HOSPITAL AND SKILLED NURSING FACILITY ADMISSION AND BILLING
HOSPITAL AND MEDICAL INSURANCE BENEFITS-SOCIAL SECURITY ACT

This report is authorized by 42 USC 139n, 42 CFR 405.1660. Your cooperation is needed to keep proper beneficiary records and to make proper Medicare payments.

NOTICE: Anyone who misrepresents or falsifies essential information requested by this form may upon conviction be subject to fine and imprisonment under Federal law.

1. Patient's last name	First name	MI	2. Sex ☐ M ☐ F	3. Health Insurance claim number
4. Patient's address *(Street number, City, State)*		Zip Code	5. Date of Birth	6. Medical record number
7. Date of this admission	8. Provider name and address *(City and State)*		9. Provider number	10. Attending physician
11. Dates of qualifying stay FROM THRU	12. Qualifying and other prior stay information			

If any of your medical expenses may be paid by your insurance organization or State Agency, complete Items 13 and 14. If you do not want information about this Medicare claim released to your insurance organization, check this block ☐

13. Name and address of organization or agency	14. Policy or Identification Number

15. Patient's Certification, Authorization to Relase Information, and Payment Request. I certify that the information given by me in applying for payment under Title XVIII of the Social Security Act is correct. I authorize any holder of medical or other information about me to release to the Social Security Administration and/or the Medicare Program or its intermediaries or carriers or to the Professional Standards Review Organizations any information needed for this or a related Medicare claim. I request that payment of authorized benefits be made on my behalf.

Signature *(Patient or authorized representative) (Signature by mark must be witnessed)*	☐ Contained in provider's record	Date

16. Admitting diagnoses	Employment Related and/or Entitlement to Other Government Programs ☐ Yes ☐ No *(If Yes, Give Name and Address of Employer and/or Program)*	Do Not use this space
17. (a) Principal diagnosis	(b) Other diagnoses	

REPORT OF ELIGIBILITY

A. Effective date—Hospital Insurance			M. Open item information 1. Intermediary
B. Effective date—Medical Insurance			
C. Hospital days remaining	Full	Coinsurance	
D. Lifetime reserve days remaining			
E. Medical Plan deductible	☐ Met	☐ Not Met	2. Provider
F. Remaining inpatient deductible			
G. Pints remaining blood deductible			
H. SNF days remaining	Full	Coinsurance	
I. 3 day hospital stay requirement	☐ Met	☐ Not Met	3. Date admitted
J. 14 day transfer requirement	☐ Met	☐ Not Met	
K. HHA visits remaining	Hospital Insurance	Medical Insurance	4. Date discharged
L. Psychiatric days remaining			

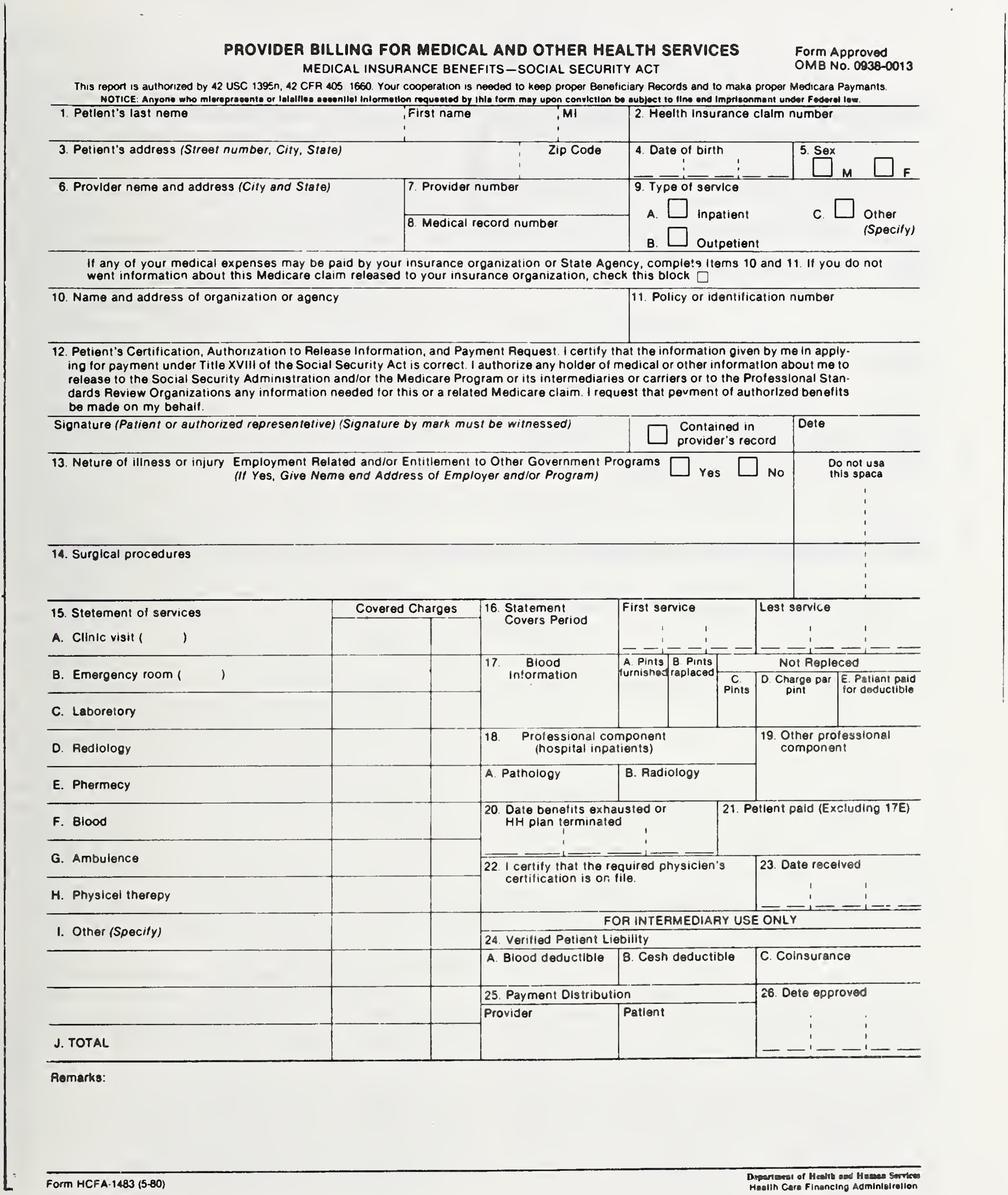
REMARKS:

Intermediary approval	Date

Form HCFA-1453(A) (U2) (5-80)

Department of Health and Human Services
Health Care Financing Administration

Appendix 15-B
Outpatient providers billing



PROVIDER BILLING FOR MEDICAL AND OTHER HEALTH SERVICES
MEDICAL INSURANCE BENEFITS—SOCIAL SECURITY ACT

Form Approved
OMB No. 0938-0013

This report is authorized by 42 USC 1395n, 42 CFR 405 1660. Your cooperation is needed to keep proper Beneficiary Records and to make proper Medicare Payments.

NOTICE: Anyone who misrepresents or falsifies essential information requested by this form may upon conviction be subject to fine and imprisonment under Federal law.

1. Patient's last name	First name	MI	2. Health insurance claim number
3. Patient's address *(Street number, City, State)*	Zip Code	4. Date of birth	5. Sex ☐ M ☐ F
6. Provider name and address *(City and State)*	7. Provider number 8. Medical record number	9. Type of service A. ☐ Inpatient B. ☐ Outpatient C. ☐ Other *(Specify)*	

If any of your medical expenses may be paid by your insurance organization or State Agency, complete items 10 and 11. If you do not want information about this Medicare claim released to your insurance organization, check this block ☐

10. Name and address of organization or agency	11. Policy or identification number

12. Patient's Certification, Authorization to Release Information, and Payment Request. I certify that the information given by me in applying for payment under Title XVIII of the Social Security Act is correct. I authorize any holder of medical or other information about me to release to the Social Security Administration and/or the Medicare Program or its intermediaries or carriers or to the Professional Standards Review Organizations any information needed for this or a related Medicare claim. I request that payment of authorized benefits be made on my behalf.

Signature *(Patient or authorized representative) (Signature by mark must be witnessed)*	☐ Contained in provider's record	Date

13. Nature of illness or injury Employment Related and/or Entitlement to Other Government Programs *(If Yes, Give Name and Address of Employer and/or Program)* ☐ Yes ☐ No	Do not use this space
14. Surgical procedures	

15. Statement of services	Covered Charges	
A. Clinic visit ( )		
B. Emergency room ( )		
C. Laboratory		
D. Radiology		
E. Pharmacy		
F. Blood		
G. Ambulance		
H. Physical therapy		
I. Other *(Specify)*		
J. TOTAL		

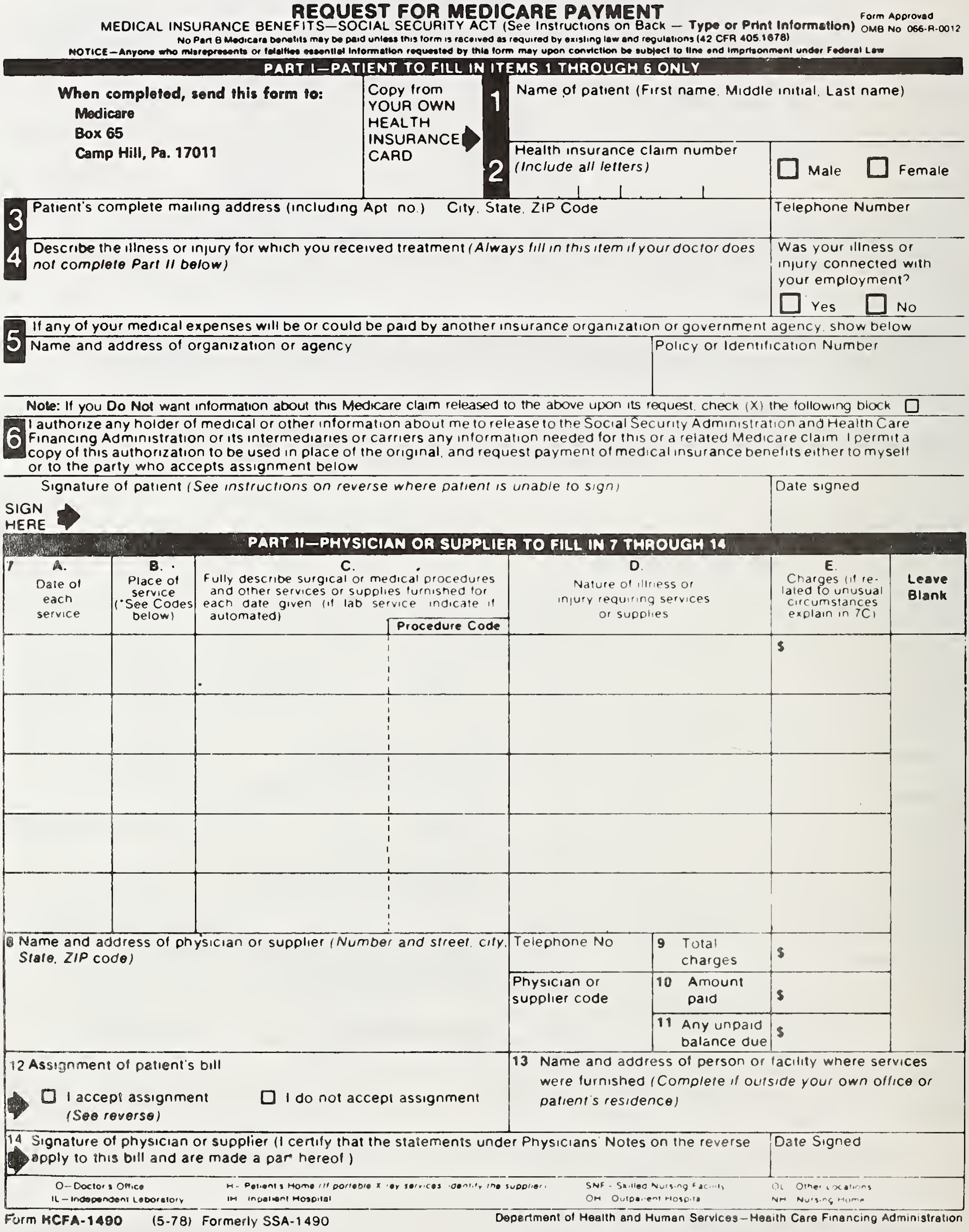
16. Statement Covers Period	First service			Last service	
17. Blood Information	A. Pints furnished	B. Pints replaced	Not Replaced C. Pints	D. Charge per pint	E. Patient paid for deductible
18. Professional component (hospital inpatients)				19. Other professional component	
A. Pathology	B. Radiology				
20. Date benefits exhausted or HH plan terminated			21. Patient paid (Excluding 17E)		
22. I certify that the required physician's certification is on file.				23. Date received	
FOR INTERMEDIARY USE ONLY					
24. Verified Patient Liability					
A. Blood deductible	B. Cash deductible			C. Coinsurance	
25. Payment Distribution				26. Date approved	
Provider	Patient				

Remarks:

Form HCFA-1483 (5-80)

Department of Health and Human Services
Health Care Financing Administration

Appendix 15-C
Physician and supplier billing



REQUEST FOR MEDICARE PAYMENT

MEDICAL INSURANCE BENEFITS—SOCIAL SECURITY ACT (See Instructions on Back — **Type or Print Information**)

Form Approved
OMB No 066-R-0012

No Part B Medicare benefits may be paid unless this form is received as required by existing law and regulations (42 CFR 405.1678)

NOTICE—Anyone who misrepresents or falsifies essential information requested by this form may upon conviction be subject to fine and imprisonment under Federal Law

PART I—PATIENT TO FILL IN ITEMS 1 THROUGH 6 ONLY

When completed, send this form to:
Medicare
Box 65
Camp Hill, Pa. 17011

Copy from YOUR OWN HEALTH INSURANCE CARD

1 Name of patient (First name, Middle initial, Last name)

2 Health insurance claim number *(Include all letters)*

☐ Male ☐ Female

3 Patient's complete mailing address (including Apt no.) City, State, ZIP Code

Telephone Number

4 Describe the illness or injury for which you received treatment *(Always fill in this item if your doctor does not complete Part II below)*

Was your illness or injury connected with your employment? ☐ Yes ☐ No

5 If any of your medical expenses will be or could be paid by another insurance organization or government agency, show below

Name and address of organization or agency

Policy or Identification Number

Note: If you **Do Not** want information about this Medicare claim released to the above upon its request, check (X) the following block ☐

6 I authorize any holder of medical or other information about me to release to the Social Security Administration and Health Care Financing Administration or its intermediaries or carriers any information needed for this or a related Medicare claim. I permit a copy of this authorization to be used in place of the original, and request payment of medical insurance benefits either to myself or to the party who accepts assignment below

Signature of patient *(See instructions on reverse where patient is unable to sign)*

SIGN HERE

Date signed

PART II—PHYSICIAN OR SUPPLIER TO FILL IN 7 THROUGH 14

7 **A.** Date of each service	**B.** Place of service (*See Codes below)	**C.** Fully describe surgical or medical procedures and other services or supplies furnished for each date given (if lab service indicate if automated)	**Procedure Code**	**D.** Nature of illness or injury requiring services or supplies	**E.** Charges (if related to unusual circumstances explain in 7C)	**Leave Blank**
					$	

8 Name and address of physician or supplier *(Number and street, city, State, ZIP code)*

Telephone No

Physician or supplier code

9 Total charges $

10 Amount paid $

11 Any unpaid balance due $

12 Assignment of patient's bill

☐ I accept assignment *(See reverse)* ☐ I do not accept assignment

13 Name and address of person or facility where services were furnished *(Complete if outside your own office or patient's residence)*

14 Signature of physician or supplier (I certify that the statements under Physicians' Notes on the reverse apply to this bill and are made a part hereof.)

Date Signed

O—Doctor's Office
IL—Independent Laboratory
H—Patient's Home *(If portable X-ray services, identify the supplier)*
IH—Inpatient Hospital
SNF—Skilled Nursing Facility
OH—Outpatient Hospital
OL—Other Locations
NH—Nursing Home

Form **HCFA-1490** (5-78) Formerly SSA-1490

Department of Health and Human Services—Health Care Financing Administration

Chapter 16.
Travel costs

Introduction

The end stage renal disease (ESRD) program of the U.S. Federal Government receives considerable attention because of its high costs. Recently, more attention has been given to the survival of ESRD patients (Weller et al., 1982; Vollmer et al., 1983; Krakauer et al., 1983). Clearly, program costs and survival are not the only dimensions on which a technology can be assessed, however. The quality of outcomes and other cost elements also deserve the attention of policymakers. The National Kidney Dialysis and Kidney Transplantation Study (NKDKTS) was funded by the Health Care Financing Administration (HCFA) to examine these other dimensions of ESRD treatment in order to provide a more comprehensive assessment. Results from an analysis of one of the often overlooked areas—travel costs (Williams et al., 1983; 1984; Seifert and Grazer, 1984) are given in this chapter.

Travel costs have two major components: transportation costs and time costs. The costs of transportation reflect the resources expended making a trip, and they include such things as gasoline expenditures, bus fares, and depreciation of a car. Time costs are simply the value of the alternatives forgone because of the time spent in making a trip. For example, a person may lose earnings because of a trip. Costs can be viewed from both a societal and private perspective. Continuing the time-cost example, the private value of the earnings lost to the individual may equal only after-tax earnings, but the societal loss includes the taxes paid.

In the past, the time costs of consuming a good or service were often ignored by economists, but recently the importance of time as a scarce resource has been recognized (Becker, 1965). A knowledge of time costs is essential to understanding consumption behavior and, in particular, has been found to be important in medical service utilization (Acton, 1975; Coffey, 1983). Upon reflection, it is obvious, especially in a service-oriented economy, that it matters to people where a service is provided—in the home or in a distant location. Travel time to the location of service provision is important to consumers in general, and travel time to dialysis facilities is important to ESRD patients (Williams et al., 1983; 1984).

In-center hemodialysis is the predominant treatment modality in this country, with nearly two-thirds of all ESRD patients on it (Chapter 4). Typically, these patients must make three trips to a dialysis facility per week; thus, at least 156 trips per year must be made to the center. These trips represent a cost to the patient and to society. Both in the patient's choice of modality and our society's choice in the location of in-center facilities, these costs are potentially important. The purpose of this chapter is to document their approximate magnitude and discuss the implications for the provision of ESRD treatment.

Methods

Patients

All 859 patients who participated in the National Kidney Dialysis and Kidney Transplantation Study were considered eligible for this analysis. All patients were grouped according to their current treatment modality—home hemodialysis (N=287), in-center hemodialysis (N=347), continuous peritoneal dialysis (N=81), and transplantation (N=133). Various characteristics of these patients have been described in Chapter 5.

Data and variables

The survey information used in this analysis comes entirely from a personal interview with the patient. A large number and wide variety of questions were asked, but the focus here is on a small set of questions concerned with travel to and from the center for treatment. Among the questions asked were:

- Did you change residence to be closer to medical facilities?
- How far (in miles and in hours) is your trip to the center?
- What transportation mode do you usually use?
- How much are your out-of-pocket expenses for travel?
- How often do you visit the center?

Valuation

Given these basic interview data on resources expended, an attempt was made to value these expenditures in dollars in order to provide a common denominator and a basis for comparison with other expenditures. The vast majority of patients travel to and from the center in automobiles. To estimate the marginal cost of transportation for these trips, an estimate of the value of the resources expended (principally, gasoline, depreciation, and maintenance) was made.

The transportation cost obviously from patient-to-patient for many reasons, including the fact that they have different cars. For purposes of this analysis it was necessary to derive an approximate average cost per mile. The U.S. Department of Transportation (1983) periodically provides estimates of the cost of operating different size automobiles. For example, in 1982 the average cost of operating a large automobile was 27 cents per mile, and subcompacts cost 19 cents. These are average and not marginal costs. They reflect a variety of costs with fixed components (i.e., that do not vary with miles driven) such as insurance, State taxes, and license fees. Marginal cost is the relevant concept for this analysis, but it is difficult to estimate how far the marginal cost is below average cost. According to the estimates, depreciation, maintenance, parts, oil, and gas represent 79 percent of the average cost of operating a large car, and 75 percent for a small car. This excludes parking, tolls, insurance, State taxes, Federal taxes, and license fees. Gas and oil alone account for between $.045 (subcompacts) and $.073 (for large cars) per mile. For purposes of this analysis, a figure of 18.4 cents per mile is used. This is the sum of depreciation, maintenance, parts, gas, and oil for operating an intermediate size car in 1982. Considering the types of cars currently in use, a reasonable guess would be that the true marginal cost lies somewhere between 15 cents per mile and 20 cents per mile when averaged across different automobile sizes.[1]

Estimating the value of the patient's time in transit is also problematic. Two different approaches are frequently used to value time.[2] The first of these, called the "human capital" approach, is commonly used in cost-of-illness studies (Hodgson and Meiners, 1979; 1982). Here, the value is set equal to the patient's gross wage, which represents what society foregoes (in terms of lost output) when the patient travels rather than works. The loss applies not only to travel time but also to treatment time. The second approach, called "willingness to pay," would attempt to value travel time by answering the question: How much would the patient be willing to pay to avoid the travel time involved in the trip (but yet receive treatment)? To illustrate by example, suppose a patient earned $8 per hour (after taxes) at work and lost an hour of work (without pay) in order to travel. Ignoring any transportation costs, the patient would be willing to pay up to $8 to avoid making the trip (assuming the trip and the job had equal effects on other dimensions, such as pleasure). In any case, the patient's willingness to pay would be less than gross wage and probably more than net wage if travel is somewhat unpleasant. Another difficulty with estimating willingness to pay arises because people may not always have a job. If not, the amount they are willing to pay might be much less than the amount they could earn at a regular job.

For purposes here, a human capital approach, taking a social perspective, is followed. In fact, this might be viewed as a form of social willingness to pay. The average gross wage for all the workers in the sample is used as the value time. The amount was $9.56 per hour. This is a very rough approximation, but it should be sufficient to provide an order of magnitude estimate, though probably an upper-bound estimate.[3]

Results

If travel costs are substantial, it is likely that they may influence not only the choice of modality but also the choice of residential location. However, for 859 respondents in this sample, only 39 (or 4.5 percent) claimed to have changed residence in order to be "closer to medical facilities." Of the 39 patients, 55 percent were currently on in-center hemodialysis. A larger proportion of patients moved for other reasons "related to kidney treatment," such as lower living expenses and special plumbing. In total, 105 patients reported changing residence as a result of kidney treatment. This represents 13.9 percent of the whole sample. To summarize, a small share of patients claimed to have changed residence as a result of end stage renal disease (ESRD) treatment. And an even smaller proportion of ESRD patients moved to save on travel costs. Thus, in general, the disruption in normal activities that accompanies both kidney disease and the participation in the ESRD program infrequently forces patients to relocate.

For those who did move closer to the facility, it is unknown how great the change in distance was. One would expect the initial average distance of the movers to be greater than that of the stayers, so there is some question as to whether they should be included in the analyses. Because they are such a small proportion of the sample and because the total sample is not necessarily representative of the U.S. ESRD population, all the observations are included in the descriptive tables. The estimates shown describe the sample after these moves have been made.

In Table 16-1, the principal modes of travel within each of the four modalities are shown. The vast majority of patients travel to their facilities by automobile, usually owned by the patient though sometimes by others. Recall that in-center patients currently constitute nearly two-thirds of all ESRD patients. Among this group, 60 percent travel in their own autos. A substantial share of in-center patients, 17 percent, use some form of public transportation other than taxi cabs. Because the vast majority travel by automobile, the cost of operating an auto is used as an estimate for their transportation costs.

Summary statistics for the basic descriptive information on travel costs gathered in this survey are given in Table 16-2. Medians, means, and standard deviations are shown for each variable for each modality. Looking first across modality, one sees the pattern for the dialysis patients that would be expected: In-center hemodialysis

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[1] In 1981, individuals with large medical expenses could be partially reimbursed for their transportation costs if they file an itemized Federal income tax return showing medical expenses in excess of 3 percent of their income. One can either deduct the actual expenses or the standard mileage rate, which was 9 cents per mile in 1982. (Cars used for business purposes, on the other hand, can use the standard mileage rate of $.20 per mile.)

[2] These two are usually presented as the two approaches to valuing life (Landefeld and Seskin, 1982).

[3] Only about one-third of the patients in the sample worked (Chapter 13), and they tend to be those who are healthy and are likely to command a higher wage. This average is above the average gross hourly earnings of $7.25 for private, nonagricultural workers in 1981 (U.S. Bureau of the Census, 1982). Finkler (1979) used an estimate of $10 per hour in valuing the travel time of heart surgery patients and their families.

Table 16-1

Percent distribution of patients with end stage renal disease, by mode of travel and treatment modality

Treatment modality	Number observations	Total	Own auto	Other's auto	Walk	Facility transport	Community transport	Cab	Bus	Other
					Percent distribution					
Home hemodialysis	284	100.0	84.5	5.6	0.4	0.0	1.1	2.8	2.5	3.2
In-center hemodialysis	338	100.0	60.1	10.9	0.9	1.5	10.7	10.1	4.7	1.2
Continuous peritoneal dialysis	81	100.0	81.5	14.8	0.0	0.0	0.0	1.2	1.2	1.2
Transplant	142	100.0	76.1	14.1	0.7	0.0	0.0	1.4	4.9	2.8

Table 16-2

Summary statistics of travel variables, by treatment modality

Treatment modality and statistic	Distance in miles (One way)	Time in minutes (One way)	Visits per year	Miles per year (Round trip)	Hours per year (Round trip)
Home hemodialysis					
Median	22.0	40.5	6.4	312.6	16.6
Mean	42.7	61.2	11.1	755.8	21.6
Standard deviation	(56.5)	(63.8)	(24.9)	(2,121.4)	(64.6)
In-center hemodialysis					
Median	9.7	20.4	155.3	3,071.2	104.4
Mean	12.7	27.5	153.3	3,895.2	140.8
Standard deviation	(13.2)	(20.2)	(12.0)	(4,084.2)	(105.0)
Continuous peritoneal dialysis					
Median	30.4	45.4	12.0	792.0	18.2
Mean	53.2	68.2	15.0	1,352.2	30.4
Standard deviation	(63.0)	(70.9)	(17.9)	(1,922.0)	(42.6)
Transplant					
Median	30.4	45.5	9.3	432.0	12.0
Mean	51.8	70.3	12.4	1,323.0	29.0
Standard deviation	(65.5)	(75.2)	(28.9)	(2,744.6)	(54.2)
F-statistic	***35.3	**33.1	***380.9	***56.5	***139.2
Number of observations	816	848	847	811	843

NOTES: **Significant at .01 level.
***Significant at .001 level.

patients live much closer (a mean of 12.7 miles) to the facility than either home hemodialysis patients (42.7 miles) or CPD patients (53.2 miles). This pattern holds as well for the median distances in each dialysis modality, and the medians are below the means in each case. This, along with the large standard deviations (over 100 percent of the means), points to great variability in distance from the center. Given these sample sizes, standard deviations, and the limitations of the sample, it would be an error to assume that these average distances apply to the general dialysis population.[4] However, the medians probably provide a better estimate of the population median. In what follows, the median is referred to as the "typical case" and is contrasted with the mean.

It is unclear why transplant patients are located much farther from the center than the in-center patients. Those ESRD patients who live farther from the center clearly have a greater incentive to seek some alternative to in-center dialysis. To a large degree this probably produces the pattern observed among the dialysis modalities, but is perhaps somewhat surprising that this is also true for transplant patients. This suggests that the choice of modality is not simply a matter of medical suitability, but may depend on other factors as well. The transplants in this sample are relatively younger, male, white, and educated, as compared with in-center patients (Chapter 5). This raises some interesting questions about the choice off modality and the impact of distance versus other factors on that choice.

The estimates in Table 16-2 show that the travel times to the facility mirror the distance patterns. In-center patients appear to be roughly one-half as far away as those on other modalities. This connection becomes

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[4] Estimates from a national probability sample (Bryan and Evans, 1978) of the dialysis population in 1978 imply greater average distances than those reported here, viz., 19.6 miles one way for in-center patients and 59.5 miles for home patients.

Table 16-3

Mean and median annual travel cost estimates, by treatment modality

Treatment modality	Total costs (A+B)	Transportation costs (A)	Value of time (B)
Home hemodialysis			
Median	$159	$58	$101
Mean	345	139	206
In-center hemodialysis			
Median	1,563	565	998
Mean	2,063	717	1,346
Continuous peritoneal dialysis			
Median	320	146	174
Mean	540	149	291
Transplant			
Median	194	79	115
Mean	520	243	277

obvious when the third column is examined: In-center patients average over 150 trips per year to the center, and those on other modalities make between 6 and 15 trips per year. Summary statistics for the miles travelled per year for this sample are shown in the fourth column. To compute this column, the number of visits per year for each patient was multiplied by the distance from the center, and then the median and means were computed. Patients who made more trips were given greater weight. In-center patients travel many more miles per year than those on other modalities. Home hemodialysis patients tend to travel fewer miles than either CPD or transplant patients.

The total hours per year spent travelling by modality are given in the last column of Table 16-2. The typical in-center patient spends 104 hours per year in travel, and the mean is 141 hours in this sample. Annual travel times for the other modalities vary from 10 to 30 hours per year. In other words, a typical in-center patient spends at least 80 hours more per year (i.e., two work weeks) in transit than those on other modalities.

Applying the appropriate valuations of transportation costs and time values to the last two columns of Table 16-2 yields the estimates shown in Table 16-3. Again, these approximate cost estimates are made from the social perspective, not the individual. The time costs to society exceed the transportation costs for all modalities, though this difference would disappear for all modalities except in-center hemodialysis if the U.S. average wage of $7.25 per hour were used as the value of time rather than the $9.56 found among the working ESRD patients. The substantial difference between in-center hemodialysis patients and other patients, however, would not be erased. The social costs of travel associated with in-center hemodialysis are between $1,000 and $1,500 greater per year than the costs associated with the other modalities.

This survey did yield some additional, but limited, information on the out-of-pocket transportation costs borne by individuals. Estimates are shown in Table 16-4.

Table 16-4

Out-of-pocket expenses for public transportation, by treatment modality

Treatment modality	Sample size[1]	Percent paying zero[2]	Percent paying some or all	Mean expenses per year[1]
Home hemodialysis	17	3.0	19.9	$ 137
In-center hemodialysis	40	20.0	20.2	1,128
Continuous peritoneal dialysis	2	10.0	9.9	630
Transplant	13	3.0	17.3	371

[1] For those in column 3, i.e., those who pay explicitly, rather than implicitly by transit in own auto.

[2] Percent of modality sample. The third group (omitted) is those travelling by own car or walking, i.e., using private transportation.

Recall that the transportation cost imputations assumed automobile transit. For the majority of patients who travel by their own automobile, and thus bear the costs in kind, no information is available on the extent to which they claim these as an itemized medical expense. For those travelling via other modes, some information was gathered on out-of-pocket expenses. Column 2 of Table 16-4 contains the percent of all patients by modality who claim to pay no out-of-pocket costs for transportation yet they travel by public transportation or in another's auto. The 20 percent of in-center patients with no out-of-pocket expenses represent approximately 13 percent of ESRD patients overall. Among those who do bear some out of pocket expenses (their percent is shown in column 3), the average expense per trip was multiplied by the number of trips per year to compute yearly out-of-pocket expenses, shown in column 4. The transportation expenses per year for these patients average slightly more than those of patients driving their own automobile (with the exception of CPD patients, where the paying sample numbers only two). If anything, these estimates accentuate the differences between in-center and other patients.

Discussion

This descriptive analysis yields two key findings. First, the costs to society of travel for end stage renal disease (ESRD) patients are not trivial. This is especially true for in-center hemodialysis, the predominant treatment modality in this country. Travel costs for in-center hemodialysis patients typically are between $1,500 and $2,000 per year. The second major finding is the substantial cost differences among modalities. Travel costs for in-center patients are far above those of other modalities, which lie below $550 per year.

The cost differences between home hemodialysis and in-center hemodialysis are a matter of long-standing controversy (Blagg, 1982; Lowrie and Hampers, 1982). The conventional wisdom has been that home dialysis is less costly. Bovbjerg and associates (1982) and Held and Pauly (1980) have argued that this may be more an accounting phenomenon than a real economic one. The estimates found in the literature are usually based on program costs to the Health Care Financing Administration. Because home patients are not reimbursed for floor space, plumbing modifications, or family members time (or own time spent in preparation), these costs do not show up as program costs, though they are resource costs to society. Furthermore, centers often perform services for home patients (such as training, retraining, supply ordering, etc.) that show up as facility costs. Held and Pauly (1980) have estimated these overhead costs to average as high as $3,000 per year per home patient.

Intuitively, at least, there is strong reason to believe that home dialysis costs society more if only these treatment-related costs are considered. Home dialysis represents extreme decentralization in the provision of the service, and facility dialysis, representing a degree of centralization, affords some economies of scale. In-center dialysis permits the sharing of aides, dialysis machines, and floor space by several patients. As suggested by these analyses, however, travel costs are another dimension that should be considered in this comparison. Decentralization reduces travel costs to society, and this reduction must be weighed against the likely increased costs in the provision of treatment.

The method used here to estimate the value of time in transit, by using the average wage of working patients, probably overstates the true average. Yet, the use of a more sophisticated method, such as imputing a value for each individual in the sample, would not alter the overall findings. Also, taking a societal, human capital perspective leads to greater costs than would be found from the aggregation of individuals' willingness to pay. The willingness to pay of individuals is likely to be much less because expected net pay from working (after taxes and disability payments are deducted) is probably far below gross pay. Furthermore, studies of travel to and from work often suggest estimates far below wages (Stopher, 1976).

This analysis has assumed that gross wage coincides with society's willingness to pay though recognizing that an unresolved controversy surround this question. The value of output lost because of time spent in transit for ESRD treatment, however, probably represents the maximum that society would be willing to pay. These costs can be viewed as one component of the potential benefits of a program that would reduce or eliminate ESRD. Or, comparing modalities, the difference in travel costs between in-center hemodialysis and transplantation represents one of the potential benefits of a program that increases transplantation.

This analysis has highlighted only one aspect—the value of time in travel—of the indirect costs of ESRD. The treatment itself often requires many hours per year (on the order of 450-750 hours for hemodialysis patients) and should be considered as well in a comprehensive assessment. Obviously, the large difference between these treatment time costs for dialysis patients versus transplant patients is a factor that makes transplantation attractive as a modality. And this time savings no doubt contributes as well to making transplant patients more likely to work, other things being equal (Chapter 13). On the other hand, transplant patients in this sample average many days more in the hospital in the first year of treatment than in-center patients do, other things being equal (Chapter 9). This represents one offset against the large differential in time costs, but it illustrates the multiplicity of elements that need to be taken into account for a comprehensive assessment.

Finally, the estimates presented here highlight another important aspect of this issue—the great variability of individual circumstances. This variation underscores the obvious point that there is no one best modality for every ESRD patient. What is best for an individual depends on the preferences of the individual (location preference being an important one).

The problem for policymakers is to design a system that is both fair and efficient. Unfortunately, this is not an easy task because the definition of fair is controversial. For example, is it fairer to give all ESRD patients an equal amount of dollars to spend on treatment or to guarantee equal access by giving a greater amount to those who live farther away from a center? Economists believe in general that competition provides the best means of achieving an efficient outcome, but their tools cannot resolve this fundamental question of equity.

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Conclusion

Chapter 17.
Economic efficiency and treatment complexities

As alluded to throughout this report, several major problems must be confronted by administrators of the end stage renal disease (ESRD) program over the coming years. Although the future of the program is not necessarily bleak, it is uncertain. Total program expenditures continue to increase largely as a function of the growing patient population and the overall composition of patients (HCFA, 1984). The immediate solution to the obvious problems are both unattractive and painful. Unfortunately, this has prompted many observers to speculate based on what might be considered the worst case scenario. Stated briefly, the suggestion is that we can no longer continue to treat the same number of patients we are today, let alone accommodate increases in the patient population (Schwartz and Aaron, 1984; Aaron and Schwartz, 1984; Evans, 1983a; 1983b; Schmidt et al., 1983).

Speculation aside, the Government is not yet openly considering elimination of the ESRD program, but the continued increase in program expenditures has spurred much interest in methods by which the program can be made more economically efficient (Bovbjerg et al., 1982; Held and Pauly, 1982). The expectation is that increased efficiency will either result in a net reduction in costs or, at least, facilitate the containment of costs. One method of accomplishing this goal in the provision of dialysis services has been to alter the rate of reimbursement to providers for each unit of service delivered. New regulations have substantially modified current reimbursement schedules (Blagg et al., 1982a; 1982b). The new regulations have proven to be highly controversial with both for-profit and nonprofit providers equally dissatisfied with the changes.

The cost of treating ESRD will continue to be at issue throughout the foreseeable future. As illustrated in this report, recently, however, greater than usual attention has focused on patient outcomes that have previously received only scant attention, including vocational and physical rehabilitation (Gutman et al., 1981; Evans et al., 1984a). Proposed initiatives intended to make the ESRD program more efficient underscore the need for data that facilitate a complete analysis of the relationship between treatment costs and patient outcomes. This analysis, as will be argued here, is absolutely essential to the promulgation of future government policy.

While there is still considerable debate surrounding the true costs associated with all major ESRD treatment modalities—home hemodialysis, in-center hemodialysis, and transplantation—various studies are now underway to better document the costs associated with each of these, the National Kidney Dialysis and Kidney Transplantation Study among them (Evans et al., 1982a; 1982b; Evans et al., 1985). A definitive statement of modality-specific costs has not been forthcoming. Estimates abound, many of them grossly inaccurate. Equally controversial have been the published studies on the outcomes of patients on each of these treatment modalities. Even though patients on some modalities, such as transplantation and home hemodialysis, appear to have a higher quality of life and a better rehabilitation rate than patients on other modalities, such as in-center hemodialysis, there is clear evidence that the association between treatment modality and patient outcomes is far more complex than indicated by past reports. Any association between modality and outcomes may in fact be attributable to one or more of several factors that include patient case-mix effects, true treatment modality effects, or unique dialysis and transplant center effects (Evans et al., 1984a; Plough et al., 1984).

In the past, the Federal Government, largely on the basis of cost and rehabilitation potential, has chosen to emphasize the utilization of certain treatment modalities, in particular, kidney transplantation and home hemodialysis. Public Law 95-292 (June 13, 1978) clearly states that "...the maximum practical number of patients who are medically, socially, and psychologically suitable candidates for home dialysis or transplantation should be so treated." Perhaps it was merely coincidental that those treatment modalities endorsed by the law were not only thought to be least costly but also had higher rates of rehabilitation associated with them.

The fact that modality-specific costs are not well-documented and patient outcomes are poorly understood poses a real dilemma for policymakers who clearly find themselves in the position of making critical resource allocation decisions in the absence of data. Many of these decisions reflect the policy objective of making the delivery of ESRD services more efficient through increased competition among providers. So far, efficiency initiatives have been targeted toward reducing services, cutting back amenities, or altering the method by which services are delivered. Since the extension of Medicare benefits to ESRD patients, legislative attempts to encourage the mass redistribution of patients to those treatment modalities that are perceived by policymakers to be least costly have been unsuccessful (Evans et al., 1981). For example, efforts to redistribute patients to home hemodialysis from in-center hemodialysis have largely proven unsuccessful. Perhaps the new ESRD regulations that inherently favor home dialysis will result in such a redistribution, but this is yet unclear. Thus, the fact that certain modalities are not being actively promoted on the basis of a quota either reflects the futility of past efforts to do so, or it serves as an indication of the general acknowledgment that adequate data are unavailable to back up past claims.

From an economic perspective, the concept of efficiency is indeed interesting. The underlying assumption is that the cost of providing a service is related to the efficiency with which it is delivered. Inefficiency results in higher costs, and efficiency serves to reduce costs. Although in principal the underlying idea is simple, the determination of efficiency is by no means simple or straightforward. This is largely because the efficiency with which a service is provided is unequivocably related to the quality of care the patient receives (Office of Technology Assessment, 1982). As services are curtailed and amenities are eliminated, in the name of efficiency, it is then appropriate to ask how quality of care is affected. If the quality of care remains unchanged, despite the reduction in or elimination of services provided, then it is safe to assume that true inefficiency existed. If, however, the quality of care is negatively affected, it must then be assumed that the very nature of the service provided, as revealed by patient outcomes, has changed. If patient outcomes have declined, then initiatives undertaken with the expressed intent of increased efficiency serve as a subtle way of letting patients know they will simply have to settle for less.

Efficiency is induced through competition. If quality of care is jeopardized through competition, then the effects of a wide array of efficiency initiatives being proposed or tested today must be carefully assessed. Although the intent of current Government-backed efficiency initiatives appears to be the removal of true inefficiency without undermining the quality of care provided, it must be assumed that alternative delivery systems will operate imperfectly.

Unfortunately, it must be ultimately recognized that there is a limit to the efficiency with which ESRD providers are able to deliver their services. Once maximum efficiency is attained, policymakers will be forced to turn their attention from how services are provided to who receives which services. Perhaps by this time, satisfactory data will have been amassed on the cost of ESRD treatment as well as patient outcomes. If so, and this report represents a step in the right direction, and it can be shown that modality-specific costs differ, then the Federal Government may once again decide to clearly state and emphasize certain treatment modalities. In an effort to be cost conscious, the least costly treatment modalities are those most likely to be emphasized. Yet it must be recognized that not all patients are equally suitable for all treatment modalities.

Over the years general patient selection guidelines have evolved for home hemodialysis, in-center hemodialysis, kidney transplantation and, more recently, continuous peritoneal dialysis. These criteria were reviewed in Chapter 1. Carefully designed studies are yet to be undertaken to determine how patients fare if they are placed on a treatment modality for which they are ill-suited. There is some evidence that inappropriately assigned patients may experience untoward outcomes or at least fare less well than if they had been placed on a modality to which they were well-matched (Evans, 1979a). For example, a good candidate for home dialysis who is placed on in-center hemodialysis may not fare as well as they would have had they been placed on home dialysis. There is also some evidence to the contrary, however. Namely, patients who are not good candidates for home dialysis but are placed on home dialysis anyway may experience better outcomes than they would have had they been placed on in-center hemodialysis (Evans, 1979b). Thus, in the name of reducing program costs, it can be anticipated that some patients may be forced to suffer, and the quality of care they receive may be suboptimal. Moreover, patients assigned to treatment modalities for which they are ill-suited may experience untoward outcomes and, consequently, could possibly incur higher costs through increased utilization. For example, misassigned patients may be hospitalized more often, require more frequent physician visits, and need a variety of social services that may otherwise not have been required had they been placed on a more appropriate treatment modality regardless of cost.

In short, regardless of how efficiency in the delivery of ESRD services is achieved, there is a real need to enter patient outcomes into the policymaking process. On the one hand, patient outcomes serve as excellent indicators of the quality of care providers deliver. On the other hand, patient outcomes are important indicators of patient suitability to available treatment modalities. These data are particularly important if policymakers begin to reassess the role of society in the delivery of ESRD services. In 1972, when Medicare benefits were extended to patients with ESRD, society in a very real sense made a commitment to treat patients without regard to cost or outcome. Today, however, society is more concerned about the wise use of increasingly scarce resources. To ascertain if resources are being so used, the relationship between cost and outcomes is a major consideration.

Many policymakers would concede that modality-specific cost data would greatly facilitate the wise use of limited resources. The solution would be simply to promote those treatment modalities that are least costly. But here again, the relationship between patient characteristics, cost, treatment modality, and patient outcomes should be a primary consideration. Not all patients will maximally benefit from the same treatment modality, with individual medical and sociomedical characteristics frequently serving as contraindications to certain treatment modalities. Thus, patient outcomes may reflect initial patient characteristics (i.e., case-mix effects) or the treatment modality they are on (i.e., modality effects). It is also conceivable that individual dialysis and transplant centers can exercise a unique effect on patient outcomes. With this in mind, cost should be a final determinant of modality choice in only those cases where it is clear that a patient is equally suitable for multiple modalities and the modalities in question have been shown to be equally efficacious, regardless of case-mix and dialysis and transplant center effects. If costs and outcomes are different, then patients should be encouraged to accept that modality from which they are likely to derive the greatest benefit, regardless of cost. If costs are the same and the outcomes are different, the patients should be similarly encouraged.

Should society ever decide that it is no longer willing to underwrite the cost of the ESRD program, then a real dilemma must be faced (Editorial, 1981). Should dialysis and transplantation be offered to all patients or only selected patients? If care is to be provided to all, then, in the face of economic constraints, it will be necessary to provide care of a lower overall quality. Less care to individual patients implies that more patients may be treated. Yet, if patients are forced to go on treatment modalities that are least costly, regardless of their suitablility and potential treatment outcome, then, as described above, they could possibly experience untoward outcomes that, in turn, would eventually result in higher program costs because of increased utilization. Thus, even though less care may have the appearance of reducing costs, in actuality, reduced costs are not realized. Consequently, the more prudent policy would be to provide high quality care to selected patients. In other words, rather than providing substandard or suboptimal care to all patients in need, it would be more medically acceptable (although, perhaps, less socially desirable) to provide care of a reasonable quality to selected patients. Such a decision is obviously frought with many ethical and social problems that have been fully described elsewhere (Caplan, 1981; Fox and Swazey, 1974; Evans et al., 1981; Fox, 1981; McCarthy and Moraczewski, 1981; Wong and Swazey, 1981; Childress, 1970; Basson, 1979; Lo and Jonsen, 1980; Abram and Wolf, 1984; Fuchs, 1984; Levinsky, 1984; Thurow, 1984). Yet, it can also be argued that the provision of care that is known to be substandard is also unethical.

To resolve the many dilemmas alluded to above, there is an obvious need for comprehensive data on ESRD patient characteristics, patient outcomes, and modality-specific costs. Additional data are also needed on the providers of ESRD services. The uses to which these comprehensive data could be put are highlighted below.

It would seem that we are in a position, once the necessary data become available, to identify subpopulations within the ESRD patient population that are likely to benefit most from one or more of the available treatment modalities. Although kidney transplantation is the treatment of choice for many patients, the shortage of donor organs will preclude giving this option to all suitable patients (Simmons et al., 1979; Guttmann, 1979a; 1979b; Sutherland et al., 1982: Kuss et al., 1982; Bart, 1981a; 1981b; Waltzer, 1983; Evans et al., 1984b; Evans, 1983c). Patients unable to receive a kidney transplant, yet suitable for one, will be forced to choose among various forms of dialytic therapy, just as patients who refuse a transplant will. The problem, therefore, will be to identify, on the basis of clinical and sociomedical criteria, which patient subpopulations are best suited to each of the following treatment modalities—home hemodialysis (Delano and Friedman, 1977; Evans, 1979a; Evans, 1978; Bryan and Evans, 1979; Blagg, 1977; Jenkins, 1976; Walker, 1977; Fine, 1984; Richmond et al., 1982), in-center hemodialysis, continous peritoneal dialysis (Harrington, 1982; Amair et al., 1982; Flamenbaum and Hamburger, 1982; Popovich et al., 1978; Nolph et al., 1980; Council on Scientific Affairs, 1982), and intermittent peritoneal dialysis (Atkins et al., 1981; Drukker, 1983). Patients for whom new and unconventional ESRD technologies, such as hemofiltration, would be appropriate would be similarly identified.

There is little basis for assuming that it is impossible to develop medical and social profiles to aid in the assignment of patients to the available treatment modalities. The indications and contraindications for all major treatment modalities, although imperfect, are reasonably well-specified. It is conceivable that, in the future, general patient guidelines may be translated into operational patient selection criteria. Although the analogy is somewhat weak, the prescription of treatment modalities for ESRD patients is similar to the prescription of pharmacological agents for any medical problem: Not all drugs are equally suited to the treatment of a patient's medical condition, nor are all drugs equally palatable to all patients. Pharmacologic agents have been defined as having specific uses with certain patients having known adverse reactions to specified drugs. Similarly, not all forms of dialytic therapy are equally suited to every ESRD patient's medical condition. For example, in the case of patients with other multisystemic diseases, such as cardiovascular disease and diabetes, continuous ambulatory peritoneal dialysis may be the treatment of choice (Harrington, 1982; Zappacosta and Perras, 1984; Amair et al., 1982). Also patient preference, both in the prescription of drugs and the prescription of ESRD treatment, is an important consideration. Thus, the task of the nephrologist in prescribing treatment modalities for ESRD is to determine which modality is best-suited to the patient's medical and sociomedical needs, as well as which modality the patient is unlikely to develop an "aversion" to. In short, the patient's medical needs must be met, and the anticipated outcomes must be favorable; that is, having minimal adverse consequences.

Assessing efficiency in the delivery of ESRD services is dependent on the availability of data on patient characteristics and outcomes, but it also requires additional data on cost. Even though data on patient characteristics and outcomes can be used to produce patient profiles, cost data must eventually be factored into the analysis to produce separate cost profiles for patients on each treatment modality. Throughout this report it has been shown that the relationship between patient characteristics, treatment modality, patient outcomes, and cost can be complex. It is conceivable, for example, that patients who are on a modality for which they are not well-suited may incur higher total medical expenses and, thus, contribute disproportionately to total ESRD expenditures than patients who are suited to their current modality. Such an association would indicate inefficiency in the provision of ESRD services, particularly in the case where Government policy requires the assignment of patients to low-cost treatment modalities, regardless of known patient contraindications. This violation of good clinical judgment in the name of economic efficiency may also be detrimental to the patient, as revealed by poor patient outcomes. Ultimately, the cost of providing care to patients mismatched or inappropriately assigned to treatment modalities may be higher and their outcomes poorer than for patients who are correctly matched to their modality.

Needless to say, much of the foregoing commentary is speculative. Unfortunately, all the data required to create the patient profiles are unavailable, as data on patient outcomes are. Although some cost data are available, they are not particularly well-suited to the proposed analyses. As described by others, the need for a data system that includes at least some of the above elements is clearly indicated (Gutman et al., 1981; Rennie, 1981). The lack of these data can do little more than perpetuate a situation where critical decisions are made either in the absence of data or on the basis of misleading or incomplete data. It would appear that the changing composition of the ESRD patient population (Evans et al., 1981), the continued increase in the number of patients treated (HCFA, 1980; 1981; 1982; 1983), the overall poorer outcomes that are being observed (Gutman et al., 1981), and the higher costs of the program (Lowrie and Hampers, 1981; 1982) would make it imperative that forthcoming ESRD program regulations be based on data suitable for clinical, medical, and ultimately management purposes. Moreover, as resource allocation and rationing decisions are sharply brought into focus, such data as those described here are particularly crucial to the application of such tools as cost-effectiveness and cost-benefit analysis (Schwartz and Joskow, 1978; Warner and Luce, 1982; Weinstein et al., 1980; Weinstein and Stason, 1976; 1977; Fuchs, 1974; 1980; Avorn, 1984; Vladeck, 1984).

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